

MADSEN **Zodiac**

901
Middle Ear Analyzer

User Manual

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Technical support

Please contact your supplier.

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1. INTRODUCTION

1.1 FEATURES OF THE ZODIAC 901

With the ZODIAC 901 Middle-Ear Analyzer, Madsen Electronics have produced a precision impedance measuring instrument which offers the busy audiologist an unprecedented level of automation, timesaving and versatility. The Limited Version of the ZODIAC 901 is described in an Addendum located at the back of this manual.

- The unique multilingual Liquid Crystal Display (LCD) reduces the required measurement data instantly to graphical, analog and concise numerical forms. The large, clear presentation of the data from each test has been optimized for rapid diagnosis of patient condition.
Liquid Crystal Display
- All function selection and pre-setting of parameters are controlled by a combination of single-function pushbuttons, plus softkeys. The five softkeys are used together with multi-choice menus displayed on the LCD. All functions are driven by the software built into the instrument. Thanks to this style of user interface, using the ZODIAC 901 can be learnt quickly and easily. This interface eliminates drudgery from the tasks of calibration and pre-test setting-up, and allows the instrument to be configured for a very wide variety of tests.
Multi-Choice Menus
- Tympanometry and reflex testing may be performed with pressure and compliance indicated in real time as a graphic Cartesian display or on analog meters, if preferred (see the display in Fig.1.1).
Analog Meter Display Option
- The ZODIAC 901 is an intelligent instrument that can be taught which tests to perform. Five Madsen Electronics Preset Tests plus the capability for four user-programmable test routines are built in, for optimal operating efficiency. The ZODIAC 901 may also be operated entirely manually or programmed for the user's own combination of manual and automatic operation. User-programmable tests enable the user to select the default parameters of a particular test. The user can also select a combination of tests to form a battery of preset tests.
User-Programmable Tests
- Intelligence in the ZODIAC 901 is not confined to its memory. If a measurement is interrupted by an air leak or acoustic interference, the instrument not only erases the data for the aborted measurement, but also keeps on re-trying the measurement from the beginning until it completes it without interruption or until the operator intervenes.
Intelligent Response To Interference
- The ZODICON™ (Madsen Electronics Zodiac Configuration) program enables your Madsen Electronics distributor to configure your ZODIAC 901 to suit your own particular needs, thus customizing the instrument into your "personal middle-ear analyzer".
ZODICON™ Configuration Program
- User-programmable test routines and custom configuration changes made using ZODICON™ are stored in non-volatile memory, and are
Non-Volatile Memory



Fig.1.1

ZODIAC 901 Middle-Ear Analyzer

preserved when the mains power is switched off. The built-in clock and calendar also continue without interruption.

Volatile Memory

- The ZODIAC 901—Version 2.x—can perform up to 36 different measurement curves on a patient (including both ears) and remember all the results (in volatile memory) until a new patient is entered or the power switched off. Version 3.x can perform/store 62 curves, and Version 4x can perform/store 72 curves.

MateBaseTM Software

- Connected via its RS232C serial interface to a personal computer running the MateBaseTM software supplied, the ZODIAC 901 can be used to store patient records in the form of a computer database.

Hard Copy Output

- The ZODIAC 901 can print out the contents of the current screen display, the results of the current test, or all the test results performed on the current patient, on the instrument's own built-in thermal printer and/or an external printer connected via the ZODIAC 901's Centronics parallel port. Printouts can include the Madsen logo, time and date, the patient's I.D. data as well as the clinic's name and address. It is especially beneficial to have the results of fast automatic screening with tympanogram, reflex and all other relevant data printed out together.

Unique Probe & Headset

- For the ZODIAC 901 Middle-Ear Analyzer, Madsen Electronics have developed a unique lightweight probe that may either be worn com-

fortably on the headset for clinical testing, or used as a hand-held probe for fast screening purposes. A smaller headband is available for testing children.

- Colored lights on the probe indicate when a measurement is in progress, and also give warning in the event of air leakage, instability in the measured ear cavity volume, or measurement interruption owing to air leakage. *Remote indication*
- The start/stop button on the probe permits remote operation of the ZODIAC 901. *Remote Control*
- Each probe supplied by Madsen Electronics has its calibration parameters and serial number stored electronically in the probe, permitting exchange of probe and/or cable without recalibration. *Built-In Calibration Data*
- The probe can be calibrated to both TDH39 and insert phone, and will automatically change from one set of phone calibration data to the other when one changes phone. *Calibration For Both Types Of Phone*
- The built-in Madsen Electronics 2 cc (2 ml) Precision Cavity enables the ZODIAC 901 to be calibrated on a daily basis to take account of barometric pressure, altitude, etc. The cavity incorporates a built-in rubber seal, enabling calibration to be performed without the use of a separate eartip. *Precision Cavity*
- Built-in Madsen Electronics' Ear Simulator allows trouble-free training and checking of the capabilities of the ZODIAC 901. *Ear Simulator*
- The comfortable, lightweight headset features a single integral cable with specially developed connectors, which carry both the electrical signals and the air-line from the pump. The stainless steel spring band and genuine leather headband enable the headset to be adjusted quickly and easily for each patient. A smaller headset for children is also available as an optional accessory. The standard TDH 39 earphone supplied may easily be replaced by an optional insert phone or bone conductor. *Headset*

1.2 APPLICATIONS OF THE ZODIAC 901

The ZODIAC 901 is designed for acoustic impedance and static pressure measurements on the ear canal. These measurements (by themselves, or in combination with pure tone audiometry) enable a variety of middle ear and other disorders to be diagnosed.

The measurement techniques embodied in the ZODIAC 901 have the advantage of being *objective*. Unlike pure tone audiometry, they depend only on passive co-operation from the patient, not on the patient's subjective judgement. They can be performed more reliably than pure tone audiometry measurements on children and other patients whose ability to co-operate may be limited.

Unlike pure tone audiometers, the ZODIAC 901 can be used successfully in environments which are not perfectly quiet, since its measuring circuits are immunized against external interference.

The ZODIAC 901 is intended for:

- Clinical tests on patients
- Screening of populations

The clinical tests which the ZODIAC 901 is designed to perform are:

- Manual/Auto Tympanometry
- Eustachian Tube Function
- Ipsi and Contra Manual Acoustic Reflex
- Ipsi and Contra Reflex Decay
- Acoustic Reflex Latency
- Pure tone audiometry (Air Conduction Threshold)
- Gellé's Test

The screening tests are:

- Automatic Tympanometry
- Ipsi and Contra Acoustic Reflex
- Ipsi and Contra Fast Acoustic Reflex Threshold
- Pure tone audiometry (Air Conduction Threshold)

The ZODIAC 901 complies with the international standards for acoustic impedance measurement referred to in its Specifications (Appendix 1).

1.3 ABOUT THIS MANUAL

Operation of the ZODIAC 901 Middle-Ear Analyzer is extremely easy and, consequently, easy to learn. This manual has therefore been designed for easy reference to specific questions or problems.

*Key Words In
Margins*

The margins contain corresponding “key words” to help you to quickly find what you are looking for, and they are all listed under a subject index at the end of the manual.

All screen instructions are reproduced as far as possible as they appear on the screen, or are shown in “screen dumps” from ZODIAC 901. Push-buttons on the instrument’s front panel are printed in the text in bold script, and shown in the margin inside a box. For example:

Manual Conventions

Press **Auto Test** to access the User Test Menu.

Auto Test

Note that default settings of various setup parameters, etc., specified in this manual, refer to those set at the factory—if your Middle-Ear Analyzer differs, this is because the default settings have been changed by your local distributor using ZODICON™.

*Default Settings
Modified By
ZODICON™*

Another feature of ZODIAC 901 is that test parameters for all tests may be changed at any time, except when a test is actually in progress. Since only those parameters valid for any particular test are displayed in the measurement setup sub-menu when **Setup** is pressed, the relevant parameters are listed in bold script at the end of the description of each test mode.

Setup Parameters

If you have any questions or suggestions with regard to the ZODIAC 901 or this manual, please contact us at the following address:

GN Otometrics A/S,
9 Hoerskaetten
DK-2630 Taastrup, Denmark.
T: +45 45 75 55 55, F: +45 45 75 55 59
www.otometrics.com

1.4 STANDARDS

The ZODIAC 901 Middle-Ear Analyzer complies with the following standards for audiometers:

EN 60645-1, -2
ANSI S3.6

The ZODIAC 901 and this manual are CE-marked according to the Medical Devices Directive 93/42/EEC.



The ZODIAC 901 is marked with this symbol to indicate compliance with Type B requirements of EN60601-1.



The device is marked with this symbol to indicate that it is electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).

In European countries the crossed-out wheeled-bin WEEE symbol reminds you that all the electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste.

You can return your device and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.

1.5 SAFETY

This operation manual contains information and warnings which must be followed to ensure the safe performance of the ZODIAC901. Local government rules and regulations, if applicable, should also be followed at all times.

Special note should be made of the following:

ZODIAC 901 is marked with this symbol when it is important that the user refers to associated warnings given in this manual.



Any PC connected to the ZODIAC 901 must comply with the requirements of IEC 950 "Safety of information technology equipment, including electrical business equipment".

1.6 SERVICE AND REPAIR

Service and repair of electromedical equipment should only be carried out by the equipment manufacturer or by authorized representatives. The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.

2. INSTALLING THE ZODIAC 901

2.1 UNPACKING AND INSPECTION

The ZODIAC 901 is shipped in its own custom-made carton together with this Operation Manual, a Packing Specification and standard accessories. Please do **NOT** dispose of this carton, in case the instrument needs to be returned to your Madsen Electronics distributor for service or repair.

Unpacking

If the shipping carton is visibly damaged, ask the carrier's agent to be present when the instrument is unpacked. If the instrument is damaged or fails to operate, please notify the carrier and your Madsen Electronics distributor immediately. The Madsen Electronics distributor will arrange for the repair or replacement of the instrument without waiting for the claim against the carrier to be settled.

Inspection

Please check that all accessories are complete and intact (referring to the enclosed **Packing Specification**).

Note that the LCD is protected by a plastic cover, which may be removed after unpacking the instrument. This cover should not be discarded!

*Protective Cover
on LCD*

2.2 STORAGE AND SHIPMENT

To protect the instrument and accessories during storage or shipment always use the best packing available. If it is necessary to return the instrument to the Madsen Electronics distributor or to the factory for repair, use the original shipping cartons and replace the protective cover on the LCD.

Storage & Shipment

Always store the ZODIAC 901 in a clean, dry environment and never leave the power on when the instrument is in an enclosed container!

When shipping the ZODIAC 901, please remember the following:

1. Seal shipping container securely.
2. Mark container **FRAGILE** to ensure careful handling.
3. In any correspondence, please refer to the instrument by **model, serial number and software version**.

2.3 INSTALLATION

**KEEP AWAY
FROM LIQUIDS!**

Site the instrument in a well-ventilated location away from all liquids and sources of heat.

Connections

Connect the headset, and, if required, the optional external printer and/or a personal computer (PC) to their respective connectors in the Connection Panel located on the rear of the instrument (see Figs. 2.1 and 2.2).

**PLEASE READ
BEFORE
SWITCHING ON!**

Before connecting the power cord, please make sure that the voltage from the electrical outlet matches the voltage shown on the identification label stuck over the power inlet.



CAUTION!
Operating at the wrong voltage may blow the fuses!

*Mains/Line
Connection*

Plug one end of the power cord supplied into the power inlet on the back of the ZODIAC 901 and plug the other end directly into a three-wire, protective ground, AC power outlet. If an extension cord is required, only use a cord with a three-prong connector.

On / Off Switch

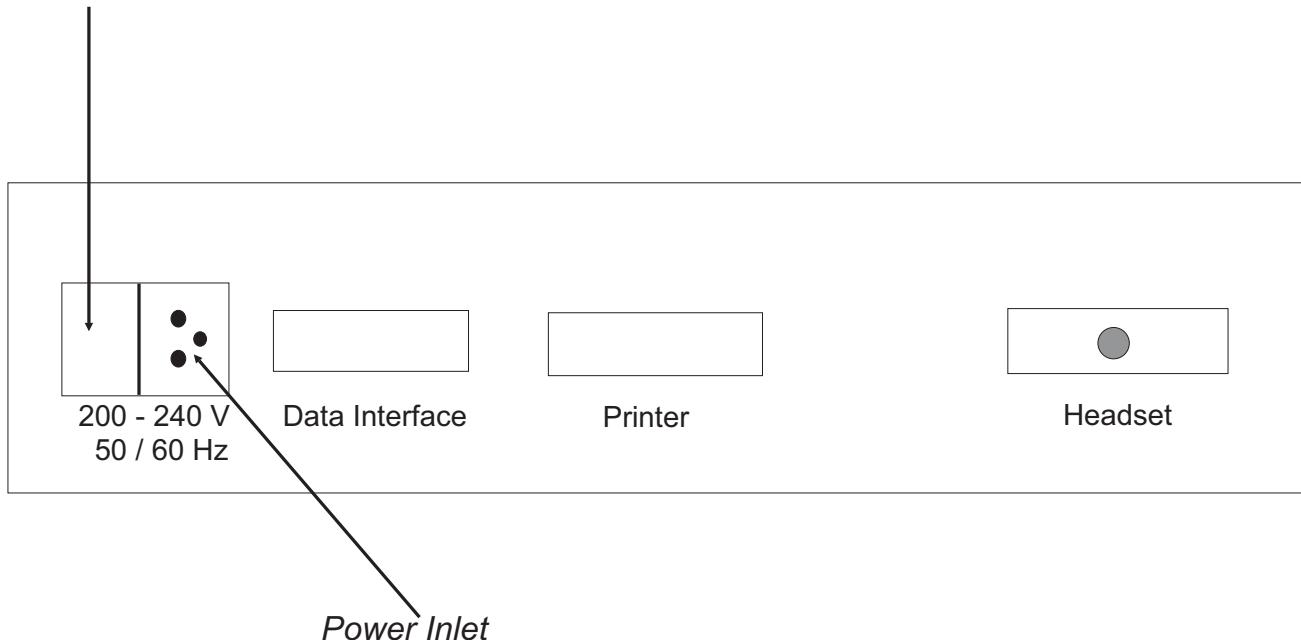


Fig.2.1

ZODIAC 901 Connection Panel.

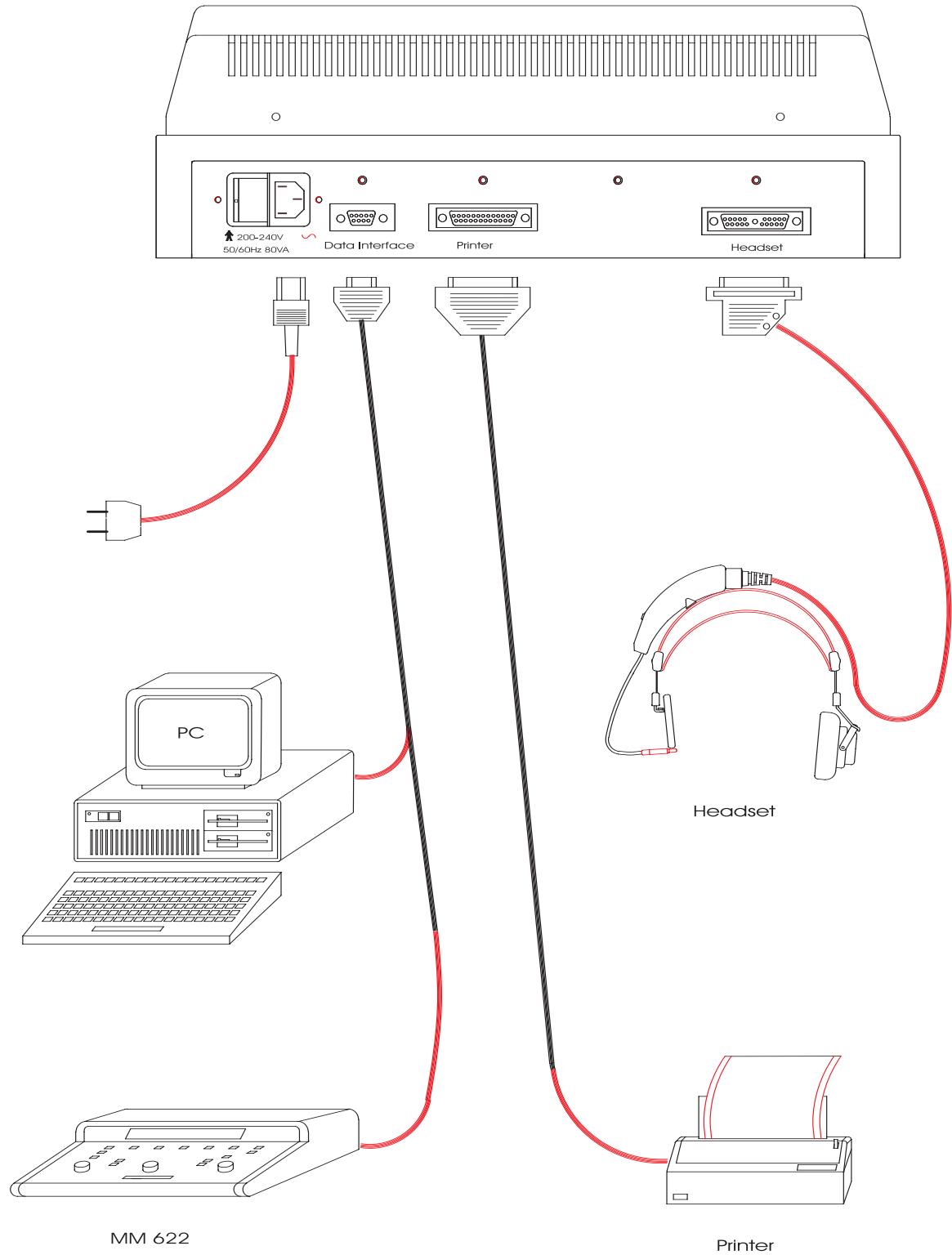


Fig.2.2

ZODIAC 901 Connections.

2.4 CARE AND MAINTENANCE

Cleaning

The ZODIAC 901 requires no preventive maintenance. However, it is recommended that the following guidelines be observed.

The instrument should be kept clean and as free of dust as possible:

Display

- Clean the LCD display periodically with an anti-static non-solvent solution using a soft lint-free cloth. Note that the display is laminated for maximum readability and must therefore be treated with care.

Protective Cover

The LCD can be protected against transport damage, i.e. scratching, by means of the supplied protective plastic cover.

- Remove dust using a soft brush and take special care to dislodge any accumulations of dirt on or around the pushbuttons on the front panel.

KEEP AWAY FROM LIQUIDS!

- To clean the cabinet and the front panel, use a soft, slightly damp cloth with a small amount of mild detergent on it. Do not allow any moisture inside the instrument!



WARNING!

Chemical cleaning agents containing ammonia or alcohol will damage the cabinet and display.

Dust Cover

If your ZODIAC 901 has been supplied with the optional plastic dust cover, you should keep the instrument covered at all times when it is not in operational use.

CAUTION!

However, the instrument should NOT be left switched on with the dust cover in place, as this may cause severe overheating and damage to the instrument. Avoid exposing the instrument to direct sunlight, and keep it well-ventilated at all times to prevent overheating.

The headset is in constant contact with your patients so care should be taken to ensure that it is kept clean, especially the earphone. Just wipe it regularly with a moist cloth.

2.4.1 CLEANING THE PROBE

Please refer to §3.5.1 for further details.

Eartips

- The rubber eartips supplied with the instrument, and available as optional accessories, are disposable. However, they may be washed an unspecified number of times in a commercial dishwasher before losing their elasticity.

- There are no special requirements for disposal of the rubber eartips.
- The probe tip must be frequently checked for cerumen (ear wax)—even a partial blockage will affect the accuracy of your measurements. Cerumen may be removed by means of the supplied metal pin (cleaning wire)—see below.

Disposal

Probe Tip

Do NOT attempt to clean any of the tubes in the probe tip without first removing the attached plastic tubes as described below.

1. First detach the probe tip from the 3 plastic tubes.
2. Use the supplied metal pin (cleaning wire) to push out cerumen from each metal tube in the probe tip.
3. Re-attach the 3 plastic tubes to the probe tip.

Procedure For Cleaning Probe Tip

2.5 FUSE REPLACEMENT

TO REPLACE A FUSE OR TO CHANGE VOLTAGE:

Voltage Select/Fuse Replacement

WARNING!

Before replacing a fuse or changing voltage, first switch off instrument and disconnect from mains power supply!



1. Switch off the instrument and disconnect from mains.
2. Remove the two Phillips screws at the back of the top panel.
3. Tilt the top panel forwards and remove.
4. The voltage selector is located next to the power switch (see Fig. 2.3 on next page). 115 V or 230 V may be selected.
5. Two identical fuses are located beside the voltage selector (see Fig. 2.3). The current of the fuses varies according to the voltage, see below:

Voltage Select

Fuse Replacement

Component	Voltage	Fuses	Type	Dimensions
F301/F302	115 V	400 mA	Slow Blow	5 x 20 mm
F301/F302	230 V	200 mA	Slow Blow	5 x 20 mm

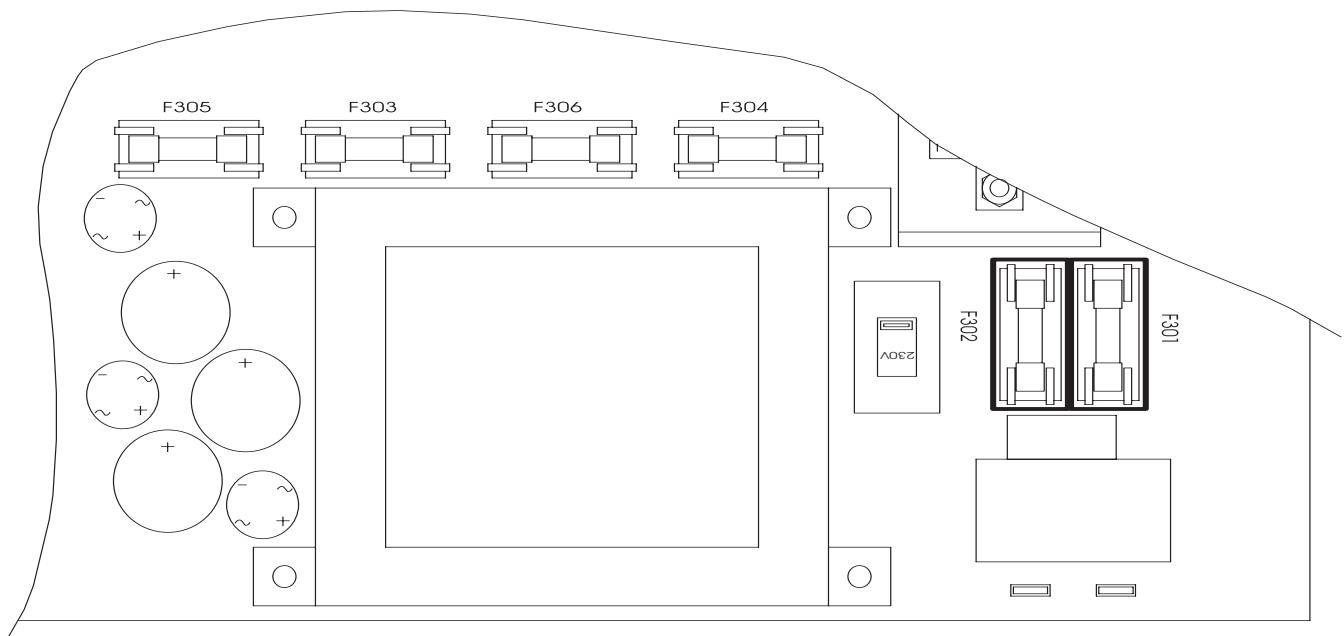


Fig.2.3

Voltage Selector & Fuses Inside ZODIAC 901.

3. GENERAL DESCRIPTION

3.1 GENERAL

Unlike most other impedance audiometers, ZODIAC 901 has no switches for selecting fundamental parameters nor potentiometers for calibration of inputs, probe, liquid crystal display (LCD), etc. Instead, parameters are selected by using pushbuttons on the front panel in combination with the display, while the conventional potentiometers have been replaced by electronic level controls which are also operated by means of pushbuttons and display.

ZODIAC 901 may be operated manually or automatically: in Manual Mode, either **Tymp.**, **Reflex** or **Threshold** is selected, and the instrument is then set up by means of the pushbuttons under the display.

Manual Mode

In Auto Mode, the various test combinations and parameters are preprogrammed (both by Madsen Electronics and the user), and may be selected by pressing **Auto Test** and then the corresponding softkey under the display.

Auto Mode

Note that toggling the Auto Test button accesses the Madsen Preset Test Menu and the User Test Menu, respectively.

Auto Test

Madsen Preset Tests may not be altered, but the User Tests may be programmed to suit individual requirements (see §7.1).

3.2 FRONT PANEL LAYOUT & CONTROLS

On the front panel there is a **Rotary Knob** for manual pump control, stimulus level control, and for setting up parameters, and a **Tone Switch** (interrupter) for administering stimuli, starting reflex tests and for entering identification data.

There are a total of 17 pushbuttons with the following functions (please refer to Fig.3.1 below).

- Five softkeys, whose functions are identified in the lower sector of each menu displayed
- Four “hard” keys for selecting the Main Menu and the three Manual Test Modes
- Three keys for Auto Mode
- Three keys for accessing the Alt. Select Menu, the context-sensitive Setup Menu, and the Printer Menu
- Keys for Air Release and Extended Range

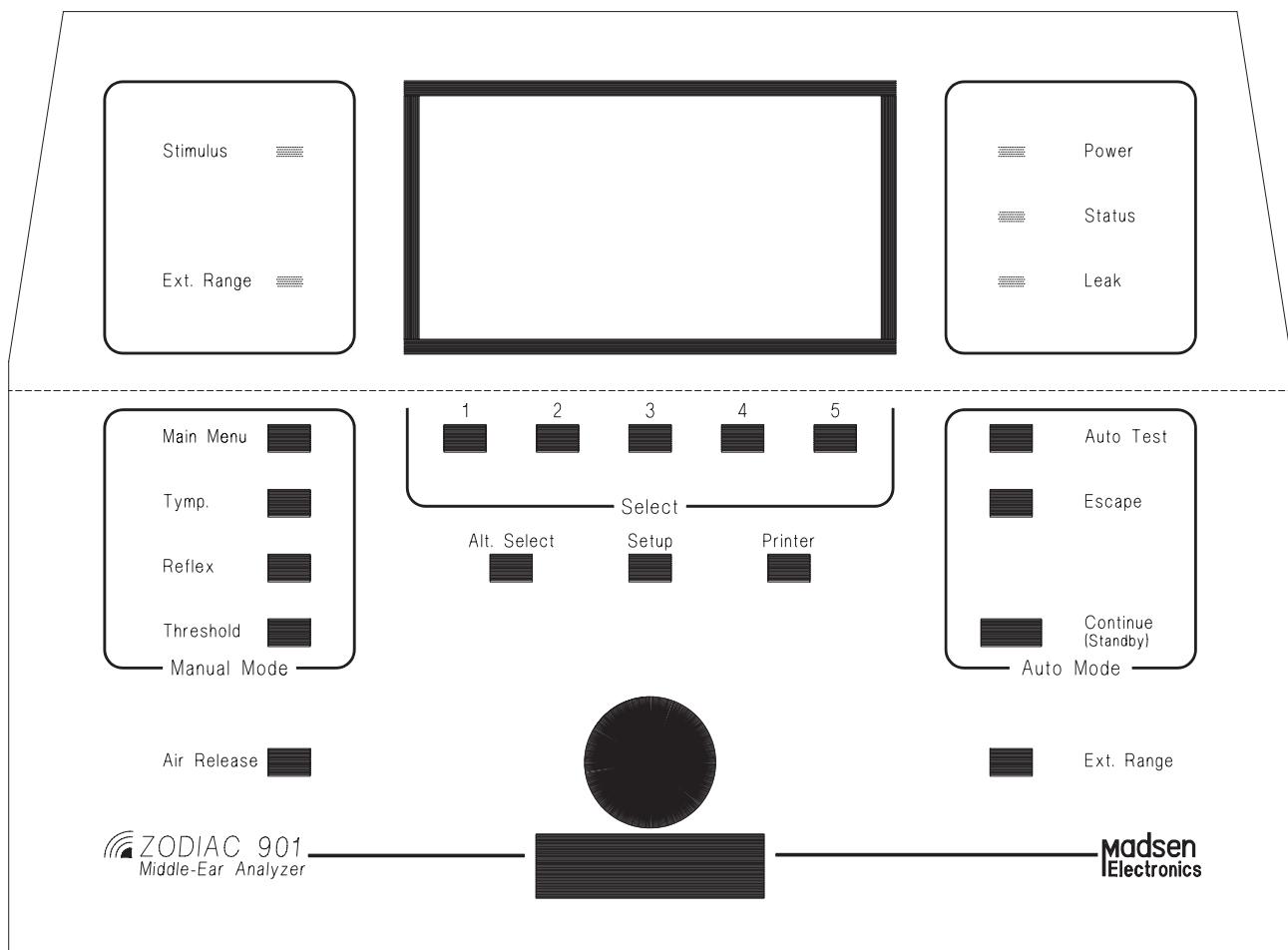


Fig.3.1

There are five indicator lamps showing Stimulus, Extended Range, Power, Status, and Leak.

In Advanced Mode, ZODIAC 901 has six principal menus which can be accessed by pressing the following pushbuttons: **Main Menu**, **Tymp.**, **Reflex** and **Threshold** in the Manual Mode and **Auto Test**. The printout submenu can be accessed from the **Printer** pushbutton.

These menus may be accessed from any point in the instrument's operation, enabling the operator to move quickly from one part of the program to another (typically after pressing a maximum of two buttons).

The front panel has been laid out for optimal ergonomic efficiency, with the different functions separated by boxes according to function.

The front panel control functions and indications are classified and described in detail in the following sub-sections.

3.2.1 MANUAL MODE

Pressing **Main Menu** displays the Main Menu. This is used to perform the following functions (see §3.4):

- Erase the current patient data and advance the patient counter ready for a new patient
- Enter identification details for patient and operator
- Perform daily calibration
- Restore default settings to cancel changes made using Measurement Setup or Auto Test sequences
- Select Easy Mode or Advanced Mode, which determine the facilities available from the other Manual Mode pushkeys

Main Menu

In Easy Mode, intermediate menus are omitted, thus speeding access to the following measurement screens:

Pressing **Tymp.** displays the Tymp. Automatic Sweep* screen in Easy Mode, or the Tymp. sub-menu, allowing additionally selection of Tymp. Manual Sweep and Eustachian Tube Function Tests (ETF-I and ETF-P), in Advanced Mode. See §.

Tymp.

Pressing **Reflex** displays the Reflex Manual* screen in Easy Mode, or the Reflex sub-menu, allowing additionally selection of Reflex Screening, Reflex Decay, User 1 and User 2, in Advanced Mode. See §4.2.

Reflex

Pressing **Threshold** displays the Threshold Reflex* screen in Easy Mode, or the Threshold sub-menu, allowing additionally selection of Fast Screening and Air Conduction, in Advanced Mode. See §4.3.

Threshold

*These are the factory default test modes. Choice of test in Easy Mode may be altered by means of ZODICON™.

ZODICON™

3.2.2 AUTO MODE

Toggling the **Auto Test** pushbutton displays, alternately, the Madsen Electronics Preset Test or User Test Menu. See §6.1 and §6.2, respectively. When a user test is being programmed, pressing **Auto Test** is used to terminate the program sequence. See §7.1. **Auto Test** is used to execute test sequences.

Auto Test

Escape

Escape is used to terminate a pre-programmed test. See §7.1.

Continue

This pushkey has two functions (as indicated on the front panel): when running a pre-programmed auto test containing one or more pauses, pressing **Continue** is used to resume the running of the program after it has paused (see §6.2 and §7.1). When the program pauses, the screen will display “Standby” and beep to show that it is waiting for a response.

Standby is used to insert a pause into a user test when required, while it is being programmed (see §7.1).

3.2.3 SELECT

Softkeys 1 to 5

The functions of **Softkey 1, 2, 3, 4** and **5** are determined at any time entirely by whichever menu which is displayed on the LCD. Every menu contains five panels, each of which identifies the current function of the key below it. In some menus, not every key has a function assigned to it.

3.2.4 ALT. SELECT AND SETUP

Alt. Select

The **Alt. Select** pushbutton accesses L/R (shift from left to right ear, or vice versa), plus the following other functions, at any time except when a test is in progress: Erase Data (but only if there is data to be erased), Tymp Smooth (not applicable in versions of the ZODIAC 901 lower than 3.x), Reflex Marker, Data Xmit (Transmit), and Contrast (for adjusting the display's contrast using the **Rotary Knob**). Press **Alt. Select** again to return to the function currently selected (except where this happens automatically). See §5.1.

L/R Ear Shift

NOTE: To select the alternate ear,
press Alt. Select and then Softkey 4.

Setup

The **Setup** pushbutton offers different sub-menus depending on which function or mode you are in at any given time. For example, if you are making a Reflex Decay measurement, pressing **Setup** will access the Reflex Decay Setup sub-menu, enabling you to alter the following Reflex Decay parameters: attenuation step; optional use of a selection of measurement levels relative to the stored level of Reflex Threshold (THL) which has previously been measured; Y-axis scaling; Y-axis origin position. Selecting **More** changes the sub-menu choices to: optional use of a measurement pressure level a selected interval above or below Middle-Ear Pressure (MEP), and Leak Detect on or off (Version 4.x). Press **Setup** again to return to the function currently selected. See §5.2.

Setup is also used for the ZODIAC 901 System Setup, which is one of the power-on options. This facility enables a large number of measurement parameters to be pre-set as required. The key is held down while the power is switched on. See §7.2.

3.2.5 OTHER FRONT PANEL CONTROLS

The **Rotary Knob** is used: to select the characters for operator and patient identification (§3.4.2); to adjust pump pressure (§4.1.1, §4.1.49.1.4, §4.2.1, §4.2.3, §4.3.1, §4.3.2); to vary Sound Pressure Level (§4.2.1, §4.2.3, §4.3.1, §4.3.2, §4.3.3); to move the marker (§5.1.6); to adjust display contrast (§5.1.5, §7.2); and to set beeper level, time and date (§7.2). It may also be used to adjust any other test parameter with more than two possible values: hold the corresponding **Softkey** down and turn the **Rotary Knob** in either direction as required.

Rotary Knob

The **Tone Switch** is used: to key in the characters for operator and patient identification (§3.4.2); to start reflex test measurements (§4.2.2, §4.2.3, §4.2.4, §4.3.1, §4.3.2); and to present stimuli for reflex testing (§4.2.1) and for air conduction testing (§4.3.3).

Tone Switch

Pressing the **Printer** key displays the Printer sub-menu, which occupies only the five panels at the bottom of the screen, leaving any test results visible. This allows selection of the internal printer (if fitted) or external printer (if connected), and disabling of printout, which overrides preprogrammed printout in the Auto tests; control of the paper in the internal printer; screen dump, which includes the relevant sub-menu; printout of the data for the current test (including data not shown on the test screen, but specified in the Measurement Setup, e.g. pump speed); and printout of all data, including test results, for the current patient, together with the Madsen Electronics' logo and, if it has been programmed, the clinic's or audiologist's custom header. See §5.3.

Printer

Pressing the **Air Release** key provides a means of rapidly relieving the pressure in the ear canal of a patient who experiences sudden distress during a test. Note that, for patient safety, this key is connected directly to the air release valve, making it independent of the microprocessor.

Air Release

The **Air Release** key also returns the pump to the middle position.

In Tymp Mode, the normal range of pump pressures for middle-ear testing is from -400 daPa to +200 daPa. Pressing the **Ext. Range** button toggles between the normal range and an extended range from -600 daPa to +400 daPa. The **Ext. Range** lamp lights red when the extended range is selected. In Reflex Mode, when extended range is selected, the maximum Sound Pressure Level of the stimulus available in Reflex and Threshold tests is also increased, from 100 dB to 115 dB in Ipsi, and from 100 dB to 120 dB in Contra.

Ext. Range

3.2.6 INDICATOR LAMPS

<i>Stimulus</i>	The Stimulus lamp lights green while a stimulus is being presented.
<i>Ext. Range</i>	The Ext. Range lamp lights red when the extended pump-pressure range of -600 daPa to +400 daPa or the extended sound pressure range are selected.
<i>Power</i>	The Power lamp lights green when the ZODIAC 901 is switched on.
<i>Status</i>	The Status lamp lights steadily green when a measurement is in progress. It flashes green if the ZODIAC 901 is waiting to make a measurement when no cavity is detected. It lights red when a measurement has been interrupted by a leak, a noise or the pump reaching the end position. This lamp is duplicated on the probe.
<i>Leak</i>	The Leak lamp lights yellow if the seal between the eartip (also called the "probe tip" or "probe cuff") and the ear canal is not airtight. This lamp is duplicated on the probe.

3.2.7 LIQUID CRYSTAL DISPLAY

<i>Liquid Crystal Display</i>	The Liquid Crystal Display (LCD) can show both textual and graphical information about the functions of the ZODIAC 901 and the results of tests. It can display tympanograms and other Cartesian graphs during measurement. For Tympanometry and Reflex measurements, the display can also emulate accurately the panels of a pair of moving-coil meters (see, for example, Fig.4.3 and Fig.4.4). Each test mode and supplementary function has its own screen display layout, which has been optimized to convey information relevant to the function.
<i>Contrast</i>	The contrast of the LCD may be altered using Alt. Select (§5.1.5) or in System Setup (§7.2). This value is saved to NOVRAM, i.e. the LCD will have the new value next time the instrument is powered on.
<i>Menu</i>	Every display layout, however, contains a lower sector consisting of a menu with five panels. Each panel shows the function of the Softkey immediately below it. At the top of each menu in the centre is a descriptive title such as "Operation" which identifies the current operating mode. The operating modes are: Select, Operation, New Patient?, Erase Data?, Select Default Configuration, Alt. Select, Setup, Printer, and Marker.
<i>Main Display</i>	The second line of the (main) upper part of every display layout also contains a descriptive title with several components, as follows:

Mode: [Activity] Ear [Earphone]

The *Modes* are: Main Menu, Identification, Daily Calibration, Tymp., Reflex, Threshold, User Test Menu, Program Mode, Real Time Clock Setup.

The *Activities* are: Manual, Sweep, Eustachian Tube Function (ETF-I, ETF-P), Screening, Decay, Reflex, Fast Screening (FastSCR), Air Conduction (AirCond).

The *Ear* is identified as Left or Right, and, in tests where it is relevant, additionally as CONTRA or IPSI. In tests which make use of an *Earphone*, this will also be identified if it is connected and Contra is selected, e.g.: "TDH39". If Contra is selected and either an insert phone or nothing is plugged in, it will indicate "insert".

In all tests where the ear canal may be pressurized or depressurized via the probe by the use of the ZODIAC 901's built-in pump, a horizontal scale appears at the top of the display during and immediately after changes in the static pressure. The purpose of this is to show graphically how much of the pump's capacity is required at any instant.

Pump capacity

In all tympanometric tests, the Volume (Vol.) of the ear canal is measured, computed and shown continuously in milliliters (ml) in one corner of the main sector of the display.

Volume

3.3 START-UP

WARNING!

ATTENTION!

To avoid damage to the probe's electronics, NEVER connect or disconnect the probe while the instrument is powered on!

1. Connect the headset via its cable to the rear panel. *Connect Headset!*
2. Plug the AC cable into the power inlet on the rear panel and then connect the analyzer to a power source. *Connect AC Cable*
3. Switch on the ZODIAC 901 by depressing the power switch (located on the left of the rear panel). *Power-On*
4. The power LED illuminates and the screen displays "Memory test" for a couple of seconds, and then which version of the software is installed and the date and time of calibration while the instrument runs an automatic self-test. The lowest line of the display indicates the status of the test and error messages, if any. *Software Version*
5. The power-up process takes about a minute, during which time the pump is run (audible click and hum), probe data is loaded, and the system memory and the calibration memory are checked. In addition, analog and electrical circuits are checked and optimized. *Automatic Self-Test*

Main Menu

6. When this process has been completed, the Main Menu is loaded and you are ready to enter your I.D. together with the I.D. of your first patient of the day (see §3.4). NO WARM-UP TIME IS REQUIRED.

Remember to Connect Headset!

NOTE: If the headset has not been connected, the analyzer will not continue and the following message will be displayed:

Headset not connected!

Error Messages

If the self-test fails or displays a specific error, make a note of the error message, call your Madsen Electronics distributor right away and report exactly what was displayed (remember to state serial no. and software version).

To Bypass Daily Calibration

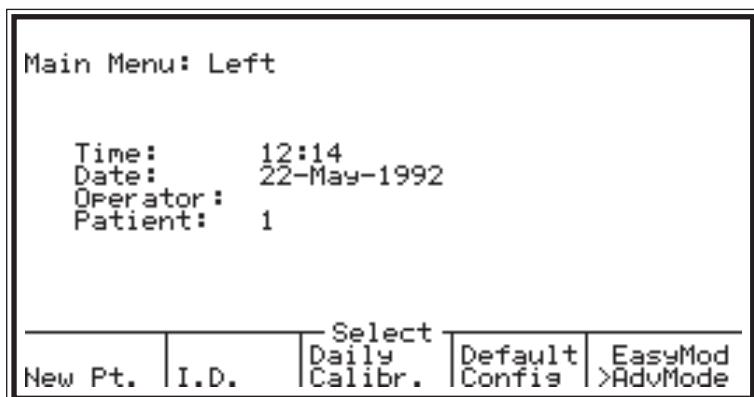
If the ZODIAC 901 has been programmed to do so by the ZODICON™ software, it may give a warning that it has not been calibrated sufficiently recently. If it has been programmed to perform Daily Calibration automatically during power-up, it may give a message requesting that the probe be inserted into the Precision Cavity. In either case, you may proceed by pressing **Main Menu**.

3.4 MAIN MENU

Main Menu

Following power-on, or after selecting **Main Menu**, the screen shown in Fig.3.2 is displayed, indicating which ear has been selected, time, date, operator I.D., patient number or I.D., and a sub-menu.

Fig.3.2



The default ear (left or right) may be set using the ZODICON™ software, and may be different from that shown in the illustration. The format of the date may also differ from that shown if it has been modified using ZODICON™. The time and/or date setting may be altered using ZODIAC 901 System Setup (see §7.2).

The following functions may be accessed from the Main Menu:

- Data from last patient tested may be erased by pressing **Softkey 1** to select New Patient.
- Selecting “I.D.” by pressing **Softkey 2** enables both operator and patient identification to be entered.
- Daily Calibration may be performed by pressing **Softkey 3**.
- **Softkey 4** enables you to “Select Default Configuration”, thus restoring the default configuration (which may have been modified using ZODICON™ software), and removing any changes made using Setup (§5.2).
- **Softkey 5** may be used to toggle between Easy Mode and Advanced Mode. This facility is used to configure the use of three of the Manual Mode keys to suit the application. In Easy Mode, the three keys select three measurement functions directly. Pressing the **Tymp.** key accesses Automatic Sweep*, the **Reflex** key accesses Manual Reflex*, and the **Threshold** key accesses Reflex Threshold*. In Advanced Mode, pressing any of these keys displays a related sub-menu which invites a further selection of tests (see §3.4.5).

Softkey 1

Softkey 2

Softkey 3

Softkey 4

Softkey 5

These facilities are described more fully in the following sub-sections.

*These are the factory default test modes. Choice of test in Easy Mode may be altered by means of ZODICON™.

ZODICON™

3.4.1 NEW PATIENT

ZODIAC 901 has a built-in automatic patient counter indicated by a number opposite the item “Patient” in the Main Menu display. Each time the instrument is powered on, the patient counter is reset at 1. If preferred, the patient may be identified by name or healthcare number (see Identification below). However, each time you finish testing a patient and wish to start a new patient, press **Main Menu** to enter the Main Menu, press **Softkey 1**, New Pt. to display the “New Patient?” sub-menu, and press **Softkey 1** again to confirm your choice.

Patient Counter

Note that the display indicates the next number on the patient counter, which you may then change to an alphanumeric entry, if desired, by returning to the Main Menu (press **Main Menu**) and pressing **Softkey 2** to select I.D.

NOTE! Selecting New Patient
erases all data on previous patient!

WARNING!

The selection of New Patient must be confirmed because all the data concerning the last patient is automatically erased from the instrument’s memory whenever you confirm selection! If a mistake has been made, pressing **Softkey 2** from the “New Patient?” sub-menu prevents the data from being erased.

*Previous Patient
Data Erased!*

3.4.2 IDENTIFICATION

Patient I.D. Entry

Entry of patient and operator identification data is enabled from the Main Menu (Press the **Main Menu** key).

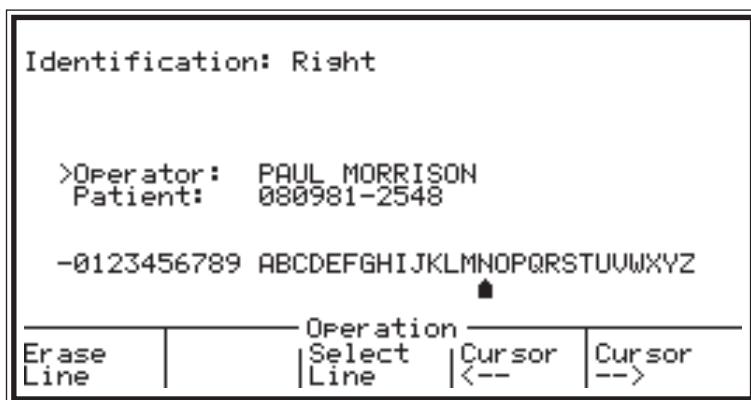
WARNING!

NOTE! Changing Patient I.D.
erases all data on previous patient!

Softkey 2

- Press **Softkey 2**, I.D., and the Identification menu, shown in Fig.3.3, appears (without name and number)

Fig.3.3



Softkey 1

- Press **Softkey 1**, Erase Line, to clear any previous data on selected line.

Softkey 3

- Pressing **Softkey 3**, Select Line, toggles between Operator and Patient.

Rotary Knob

To enter I.D. data, press **Softkey 3** if necessary to select the required line, turn the **Rotary Knob** until you find the desired character, and press the **Tone Switch** to enter the character. Pressing the Cursor arrow buttons (**Softkeys 4** and **5**) moves the cursor to the right or left on each line (max. 21 characters). If you make a mistake, return to the incorrect character(s) by means of the Cursor arrow buttons and overwrite the incorrect character(s).

The following characters are available: hyphen, 0-9, space, A-Z.

To Exit Identification
Sub-menu

Return to the Main Menu by pressing **Main Menu**.

3.4.3 DAILY CALIBRATION

Your ZODIAC 901 is delivered to you fully calibrated, and should be recalibrated annually by suitably qualified personnel, using the appropriate equipment. Your instrument may have been configured by means of ZODICON™ to remind you when this period has expired.

*Annual
Recalibration*

Your ZODIAC 901 is dispatched from the factory in Denmark together with a Test Report (Calibration Certificate). The Test Report specifies which transducers have been calibrated (i.e. those which have been supplied together with the instrument), according to which standards, and what equipment was used for calibration. Results are listed for each transducer at all standard frequencies.

Test Report

In general, the instrument is calibrated in dB SPL or dB HL using the stated reference equivalent thresholds; dB HL are related to sound pressure levels, db SPL = dB re 20 μ Pa. (1 cc = 1 ml).

Note that calibration has only been performed on the supplied transducers! If you wish to use any other transducer for testing with the ZODIAC 901, please contact your local Madsen distributor first.

However, since the weather and barometric pressure vary from day to day, the probe measuring system should be calibrated on a daily basis in order to achieve the greatest possible measurement accuracy.

With the ZODIAC 901, this procedure is very quick and easy to perform (maximum 15 seconds); just press **Softkey 3** from the Main Menu to access the screen shown in Fig.3.4:

Softkey 3

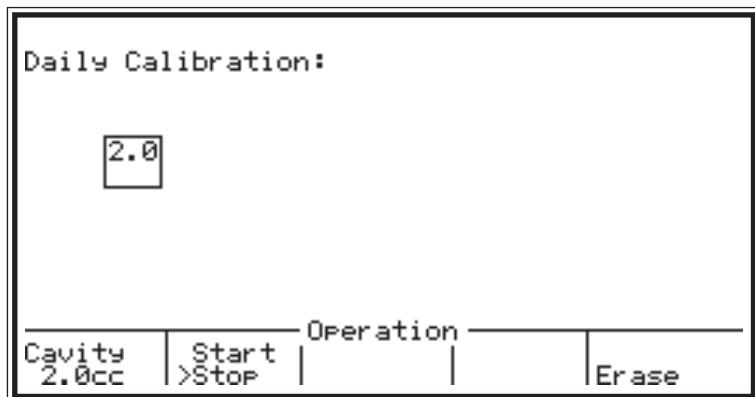


Fig.3.4

If provision for calibration with a second Precision Cavity having a different volume from the default has been programmed using ZODICON™, **Softkey 1** may be used to toggle between the two cavities. The volume of the cavity selected is shown in the small box on the left of the display.

Softkey 1

Insert the probe into the 2.0 cc (= 2.0 ml) Madsen Electronics Precision Cavity located in the left side of the ZODIAC 901's cabinet. (Do not insert it into the Madsen Electronics Ear Simulator.) Press **Softkey 2** (or the Start/Stop Button on the Probe) to start the calibration. The Status lamps on the Front Panel and the Probe light steadily green during cali-

Softkey 2

bration. After a few seconds, an X appears under the cavity volume in the box on the left of the display, indicating that the procedure has been completed. If the **Status** lamps flash green slowly, check that the Probe is not blocked with cerumen (wax), or has not been inserted into the Ear Simulator by mistake.

Softkey 5

To re-calibrate without powering off the instrument, press **Softkey 5** to erase the existing calibration and repeat the procedure described above.

3.4.4 DEFAULT CONFIGURATION

Softkey 4

Pressing **Softkey 4** invokes a menu called "Select Default Configuration". This allows changes made using Setup (see §5.2) to be cancelled, in favour of the default. Press **Softkey 1**, "Yes", to do this. (Note that your default configuration may have been programmed using ZODICON™ software.) If cancelling changes which have been made using Setup is not what is required, press **Softkey 2**, "No".

3.4.5 EASY AND ADVANCED MODES

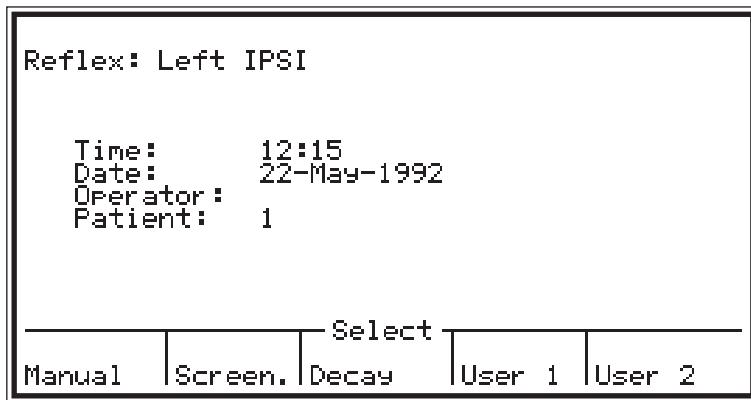
In Manual Mode, tympanometry, reflex and threshold testing are accessed by pressing the appropriate pushbutton on the left of the front panel. However, the screen that appears in either one of these three test modes depends on whether Advanced or Easy Mode has first been selected in the Main Menu. This selection is stored in NOVRAM, i.e. the instrument will power on with the last selection active.

In Advanced Mode

In Advanced Mode, an intermediate sub-menu appears at the bottom of the screen offering you the following choices (for an example, see the Reflex sub-menu illustrated in Fig.3.5).

Tymp.: Manual Sweep, Auto Sweep, ETF-I,ETF-P
Reflex: Manual, Screening, Decay, User 1, User 2
Threshold: Reflex, Fast Screening, Air Conduction

Fig.3.5



In Easy Mode, these sub-menus are omitted and instead the following test modes are entered ready for immediate testing (unless the selection has been previously modified using the ZODICON™ software):

Easy Mode

Tymp.:	Automatic Sweep
Reflex:	Reflex Manual
Threshold:	Reflex Threshold

3.5 HEADSET AND PROBE

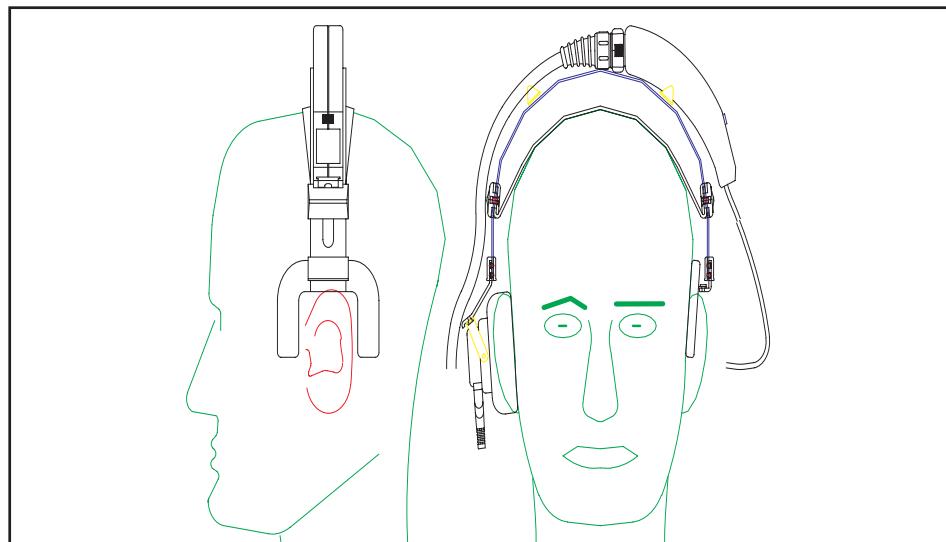
One of the unique features of the ZODIAC 901 Middle-Ear Analyzer is the novel headset with detachable probe and integrated cable, which permits patients to be tested with or without headset depending on whether they are being screened or subjected to a clinical examination.

The probe assembly consists of 3 parts: the probe itself on to which the eartip is mounted, the transducer or probe handle and 3 small plastic tubes connecting the probe and transducer.

Fig.3.6 illustrates the headset with probe attached. The headset may be adjusted to suit the geometry of the patient's head by sliding the buckles which fasten the leather strap to the headset up or down the stainless steel spring band.

The pushbutton on the transducer duplicates the function of **Softkey 2**

Remote Control From



*Fig.3.6
Probe and Headset*

in the measurement modes which have a start/stop function, i.e., as a start/stop button. The two LED's indicate duplicate the functions of the **Status** and **Leak** LED's on the top right of the front panel. The **Status** lamp lights steadily green when a measurement is in progress. It flashes green if the ZODIAC 901 is waiting to make a measurement when no cavity is detected. It lights red when a measurement has been interrupted by a leak.

Probe

*Calibration Data In
Probe*

It should be stressed that the calibration data for the probe are located in the transducer itself and are loaded from the probe into the instrument's memory immediately after power-on ("Loading from headset...").

Probe Replacement

This means that any replacement of probe assembly does not require any lengthy calibration procedure, but simply a power-on after the new transducer has been connected. The probe assembly may easily be detached from the instrument by detaching the connector from the rear panel.

*Avoid Detaching
Transducer From
Cable!*

However, the practise of repeatedly detaching the transducer from the cable is not recommended since this could affect the integrity of the air pressure system.



WARNING!
**ZODIAC 901 must be powered off BEFORE disconnecting either
transducer or transducer cable.**

3.5.1 EARTIPS

Eartips

The ZODIAC 901 is supplied with a set of different sized soft plastic eartips (also called "probe tips" or "probe cuffs") which fit over the end of the probe and permit an airtight seal in the patient's ear canal.

*Sanitization Of
Eartips*

Each tip should be used on only one patient, and then sanitized by washing in warm soapy water. Eartips should then be rinsed and allowed to dry before reuse. Each tip has a limited life and should be discarded once it becomes difficult to achieve a reliable seal.

Probe tips from other manufacturers may fit the ZODIAC 901 probe, but they have not been tested by Madsen Electronics and we therefore cannot make any recommendation regarding their use.

3.5.2 USING THE HEADSET AND PROBE

The ZODIAC 901 probe is designed to provide the user with a choice of three ways in which it may be supported in use:

- The transducer may be mounted on the headset. Dimples on opposite sides of the transducer engage in a pair of lugs on the saddle-shaped clip on top of the headset. The transducer cable should be pressed into the clip provided for it on top of the headset. The miniature jack plug connecting the TDH 39 earphone may be plugged into the socket on the side of the transducer. The probe itself is connected to the transducer by three fine plastic flexible tubes. If the probe is attached to the transducer, slide the small slotted cover in the end of the transducer upwards, and gently pull the probe out. Take care not to pull the tubes.

- The transducer may be held in the hand and used to guide the probe into the patient's ear canal. This is most practical for fast screening of patients, as the transducer must be supported all the time. If the probe is not fixed to the transducer, slide the small slotted cover in the end of the transducer upwards, position the probe so that the flexible-tube attachments lie snugly in the recess in the bottom of the transducer, and gently push the probe backwards into the transducer until resistance is felt. Slide the slotted cover back to lock the probe in position.
- The transducer may be held in the hand while the probe, connected to the transducer only by the flexible tubes, is inserted (with an eartip) into the patient's ear.

CAUTION!

On no account should the integrity of the three plastic tubes be violated.

CAUTION!

Before inserting the probe into the patient's ear, make a careful inspection of the ear to identify any possible problems. If necessary, brush the patient's hair away from the ear to gain a clear view. Gently pull the earlobe (*pinna*) back and press the *tragus* forwards towards the face to inspect the part of the ear canal which will be in contact with the eartip. **Excessive ear wax will interfere with the measurement and block the probe channels.** Other foreign objects and dirt could have similar undesirable consequences. Remove them. Sores, cuts or warts could lead to patient distress during measurement. Signs of blood or pus could indicate infection.

Inspection Of The Patient's Ear

Excessive growth of hair around the ear canal may make an airtight seal impossible. The **Leak** lamp on the probe will light if this problem occurs during an automatic measurement. It may be possible to cure a leak with a smear of petroleum jelly, but too much of this is likely to block the probe channels.

Choose an eartip of a suitable size and insert the probe into the narrower end of the eartip first. When inserting the probe and eartip into the ear canal, pull the earlobe back to straighten the ear canal, and at the same time ask the patient to open the jaw, as this will have the effect of widening the ear canal. Rotate the probe and eartip during insertion, as this will facilitate entry and reduce patient discomfort.

Although tymp. and reflex measurements made using the ZODIAC 901 are less vulnerable to errors resulting from unwanted noise than pure-tone audiometry measurements, it is nevertheless important that the patient keep quiet during a measurement. This is especially important during reflex measurements, where small changes in compliance are measured in real time. If the transducer is being held in the hand, keep it still and avoid adjusting the eartip while a measurement is in progress, to prevent microphony. Noisy office machinery in the room should be switched off, and conversations terminated. A patient with a cold may usefully be invited to clear his throat and blow his nose before the measurement begins (whereafter the patient must equalize pressure prior to

measurement). If unexpected noises occur during a measurement, repeat the measurement when the interruption has ceased.

Before making a tympanometry measurement, tell the patient reassuringly to expect a change of pressure in the ear, and tell him about the probe tone. Before measuring reflex, warn the patient about the sudden onset of the stimulus.

Remember To Change Ear On ZODIAC 901!

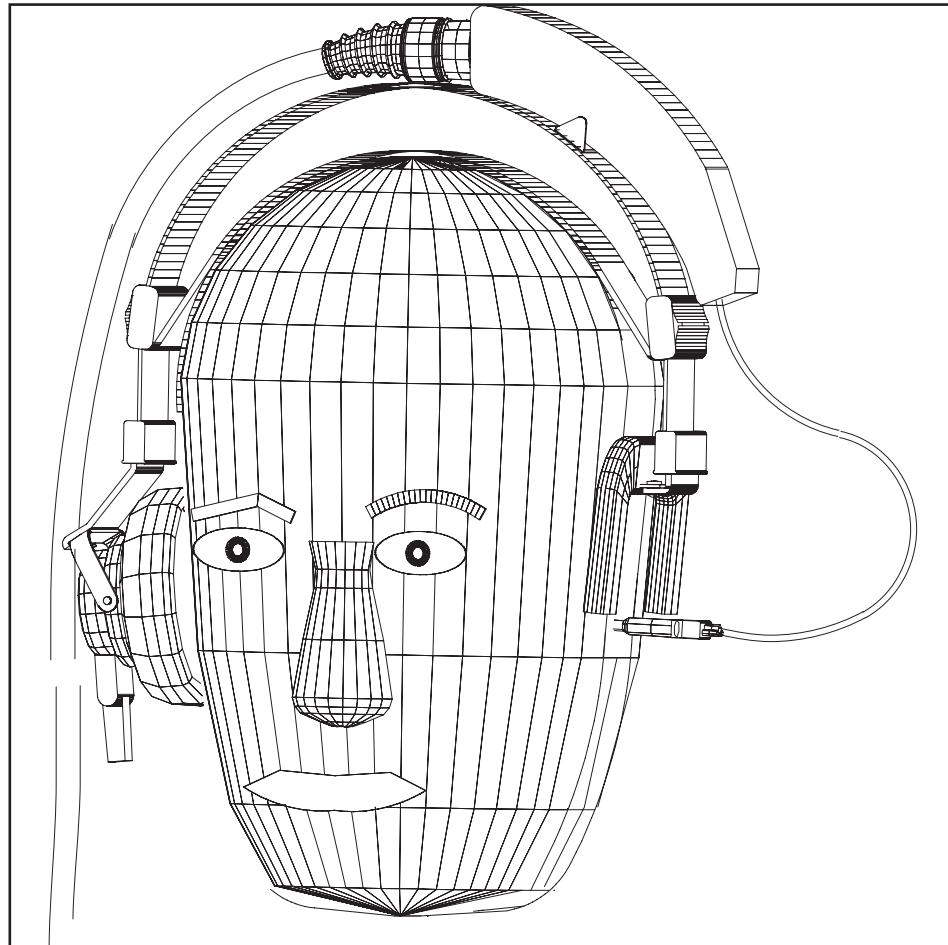
When starting to test the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will be overwritten. The ear to be tested may be selected as follows:

1. Press Alt. Select.

2. Press **Softkey 4** to toggle between left and right.

The ear selected (Left or Right) is displayed in the uppermost line of the Main Menu and every other menu associated with a measurement.

Fig.3.7



4. MANUAL MODE

ZODIAC 901 features three dedicated pushbuttons, **Tymp.**, **Reflex** and **Threshold**, enabling the user to access any of the corresponding three test modes from any other function or part of the instrument.

From any test in Manual Mode, you may press **Setup** to access the Measurement Setup sub-menu, thus enabling you to change whichever test parameters are valid at that given time. The relevant parameters are listed after the description of each test given below.

Setup

NOTE: The **Setup** pushbutton is inactive while a test is in progress, i.e. nothing will happen if this button is pressed during a test.

*Setup Inactive
During Test!*

Pressing one of the three Manual Mode pushbuttons accesses a sub-menu when Advanced Mode has been selected from the Main Menu, enabling the user to select the desired test. This Chapter describes how to perform each of the range of tests available from these menus.

If it is required to erase the current test data, smooth a tymp. curve (Cartesian graph, not available with Version 2.x of the ZODIAC 901), access the marker function, transmit data to an external computer, register a change of ear, or adjust the contrast of the Liquid Crystal Display, press **Alt. Select** at any time except while a measurement is in progress (see §5.1).

Alt. Select

The ZODIAC 901 Middle-Ear Analyzer incorporates a pump which is used to apply a small static pressure or depression to the patient's ear canal. Although this pressure is no more than would be experienced by ducking one's head just below the surface of the water in a bath, it may occasionally be sufficient to cause unexpected distress to a patient with an ear disorder. The pressure may be relieved promptly by pressing the **Air Release** button, which automatically resets the pump position.

Air Release

Most of the parameters used in the following tests which can be set by pressing a **Softkey** repeatedly can also conveniently be adjusted by holding the same **Softkey** down and turning the **Rotary Knob** in either direction.

4.1 TYMPANOMETRY

Tympanometry is the measurement of the variation of the compliance (or immittance) of the eardrum and the ossicular chain by means of controlled changes in static pressure. A graphic plot of these parameters is called a tympanogram. The ZODIAC 901 can be used to perform manual tympanometry and generate tympanograms directly, for display on the screen and printing out on paper (see §5.3).

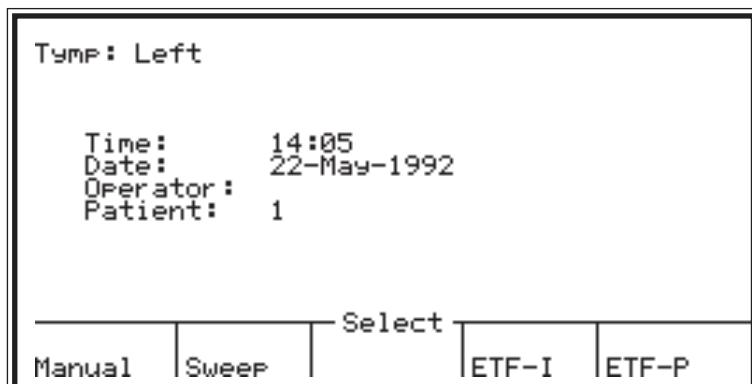
Among the disorders which can be indicated or confirmed by tympanometry using the ZODIAC 901 are: ossicular discontinuity; otosclerosis (rigidity in the ossicular chain); flaccid (hyper-mobile) eardrum due to aging; perforated eardrum; obstruction of the ear canal; middle-ear fluid; dried ear-wax; Eustachian Tube dysfunction.

Tymp.

In Advanced Mode, the screen shown in Fig.4.1 will be displayed when Tymp. is pressed.

Fig.4.1

Tymp. Sub-menu displayed when Tymp. Is selected in Advanced Mode



If Easy Mode has been selected, pressing Tymp. will display the Auto Sweep screen illustrated in Fig.4.5 (unless this has been altered using the ZODICON™ software). In Advanced Mode, the following operation modes may be selected from the Tymp. Menu: Manual, Auto Sweep, and ETF (Eustachian Tube Function test, perforated eardrum). Version 3.x of the ZODIAC 901 includes another ETF test, Intact (Eardrum), which is not included in Version 2.x, and is used to test the Eustachian Tube Function in patients where the eardrum is intact.

If the default has been altered using the ZODICON™ software, the following Tymp. defaults may differ from the settings shown in the illustrations: compliance scaling, absolute volume scaling, sweep pump speed, sweep measurement direction, manual measure direction, leak detect, minimum sweep pressure, and maximum sweep pressure.

Version 4.x Only

From Version 4.x of the ZODIAC 901 (including the Limited Version), a Middle-Ear Pressure (MEP) marker has been implemented in Tymp Auto Sweep and ETF-I testing. Softkeys 4 and 5 no longer are used for moving the pump, but for moving the marker instead. When moving the MEP marker, the current values for MEP, SC, Gradient and TW are displayed in real time on the left of the screen. An asterisk appears to the right of the MEP value to indicate that the marker has been moved.

4.1.1 MANUAL

This test permits the user to operate the instrument manually. Both Compliance and Volume tympanograms may be generated. Pressure may be altered and volume adjusted to zero at any point in the test.

Press **Main Menu** and use **Softkey 5** to select Advanced Mode (unless this requirement has been changed using the ZODICON™ software). Press **Tymp.** and then **Softkey 1** to access the screen shown in Fig.4.2.

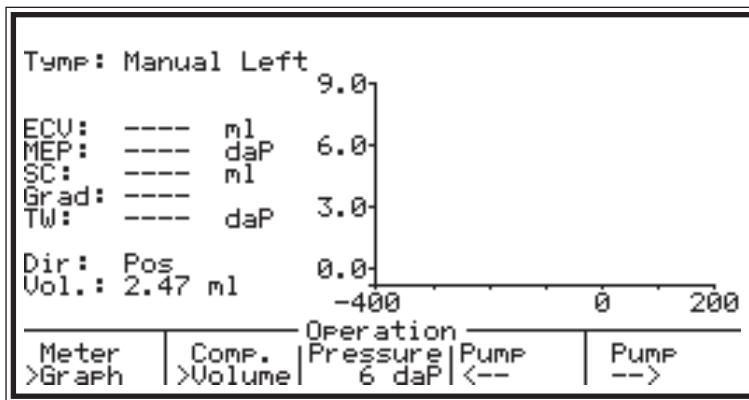


Fig.4.2

Tymp. sub-menu displayed when Tymp. is selected in Advanced Mode
Tymp. Manual before measurement

"Vol." shows the cavity volume measured at the pressure shown in the center panel. "ECV" = Ear Canal Volume. "Comp." = Compliance, i.e., the volume change relative to the ECV. Thus Vol. = ECV + Comp. ECV is shown only when Comp. is selected. The vertical scales are in milliliters; 1 ml = 1 cc.

NOTE: The Tymp. screens of software versions lower than 3.x do not include fields displaying calculated values for: MEP, SC, Grad., TW nor Dir.

Software Version 3.x and Higher Only

After a satisfactory Tymp. measurement has been made, and Comp. is selected, a screen similar to that shown in Fig.4.3, containing the measured tympanogram, will be seen.

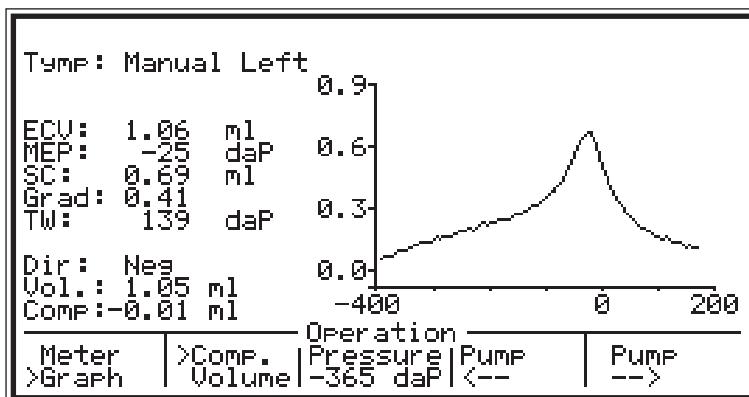


Fig.4.3

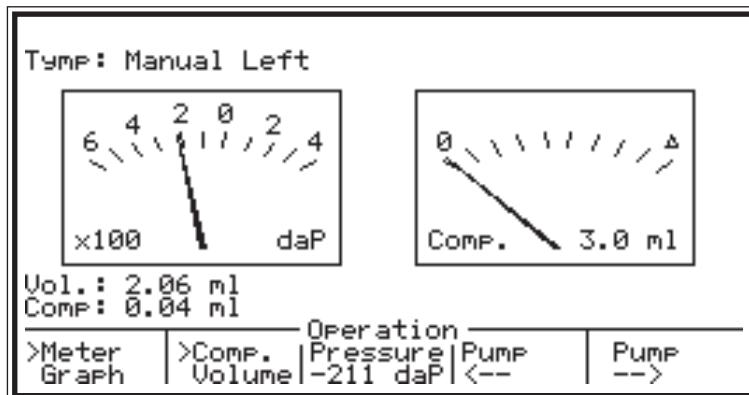
Tymp. Manual after measurement

Softkey 1

Users who find it more informative to perform tympanometry using analog meters instead of the graphic display of a tympanogram can press **Softkey 1**, and a screen similar to the one shown in Fig.4.4 below will appear.

Fig.4.4

Tymp. Manual analog meter display

**Softkey 1**

Note that pressing **Softkey 1** again after completion of the tymp. measurement will return you to the graphic display and show you the tympanogram you have just made using the analog meters.

Softkey 2

Press **Softkey 2** to record the ECV and display a Compliance tympanogram instead of a Volume tympanogram. The measured values of ECV and Compliance at the current pump pressure are shown on the upper left of the graphic display. The ECV (and thus the *y*-axis origin on the Compliance tympanogram) may be reset at any value of pump pressure by toggling **Softkey 2** back to "Volume".

Softkey 3

Softkey 3 has no effect during this measurement. The current pump pressure is displayed in the window above it.

Rotary Knob

The pump pressure may be set by turning the Rotary Knob. A scale will appear temporarily at the top of the display to indicate the pump position graphically. This shows what proportion of the pump's capacity is used to obtain the static pressure used for the measurement.

Softkeys 4&5

The pump pressure may also be reduced or increased by pressing **Softkey 4** or **Softkey 5**, respectively. The Status lamp will light while this is being done. Holding either key down causes the pressure to change continuously in the direction of the arrow shown in the window above the key.

Air Release

To restore the static pressure to zero quickly, press **Air Release**, which automatically resets the pump position.

L/R Shift

Before testing the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will be overwritten. Press **Alt. Select** and then **Softkey 4**.

Ext. Range

Note that the pressure range of -400 to +200 daPa may be expanded to -600 to +400 daPa by pressing **Ext. Range**.

Setup parameters available in Manual Tymp. Mode are:

Setup Parameters

Measuring Direction: positive/negative, pos., or neg.

Y-axis Scaling (Compliance): Auto, 0.3 ml, 0.6 ml, 0.9 ml, 1.5 ml, 3.0 ml, 4.5 ml.

Averaging: On/Off (not Version 2.x)

The **Alt. Select** pushkey allows you to use the Smooth feature to optimize the curves (see Fig.4.10 and refer to §4.1.35.1.2 for further details re this function). Just press **Softkey 2** from the Alt. Select sub-menu.

Alt. Select

4.1.2 AUTO SWEEP

In this test, a sweep is automatically performed and a Compliance tympanogram generated when a volume is detected (until a volume is detected, the green **Status** lights on the front panel and probe will flash). In effect, this enables you when testing children to initiate the test even prior to inserting the probe into the patient's ear.

Auto Sweep

If there is a leak before the sweep starts, the **Leak** lights on the front panel and probe will light yellow. Before proceeding, ensure that you are using the right size eartip, and try pulling down the ear lobe while at the same time rotating the eartip in the ear canal. Meanwhile the analyzer will continue to attempt a sweep until the pump reaches the end position whereupon the Status lamp lights red until the pump is reset. Then the instrument will continue the procedure automatically. If Leak Detect has been disabled (Version 4.x only), the analyzer stops after one sweep (see Setup, §5.2.1).

Leak

It is worth noting that in Version 3.x and later, a leak encountered after the sweep begins provokes a beep and the **Leak** lights go yellow. If Gradient and TW can be calculated on the basis of the interrupted sweep, the test is halted and the relevant data displayed. If not, the analyzer will repeat the test as described above.

Leak Detect On/Off

Press **Tymp.** and then **Softkey 2** to access the screen shown in Fig.4.5. Press **Softkey 2** again (or the Start/Stop Button on the Probe) to start the test.

Version 3.x Only

During the sweep, a scale at the top of the display indicates the current pump position graphically, i.e., what proportion of the pump's capacity is used to obtain the static pressure used for the measurement. Both the pressure range and the direction of the sweep are selectable under Measurement Setup (see page 35). Pump speed is also selectable and includes the function AFAP (As Fast As Possible—please refer to page 36 for further details).

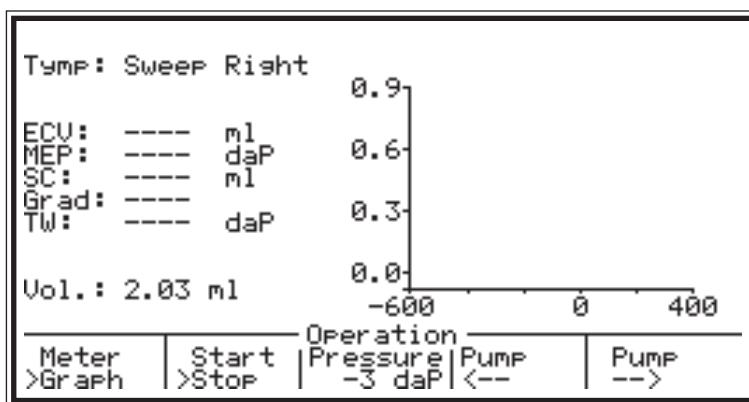
Pump Pressure

When the sweep is completed, the computed values for Ear Canal Volume (ECV), Middle Ear Pressure (MEP), Static Compliance at MEP (SC), Gradient (Grad) and Tympanogram Width (TW) are shown on the left-

Softkey 2

Fig.4.5

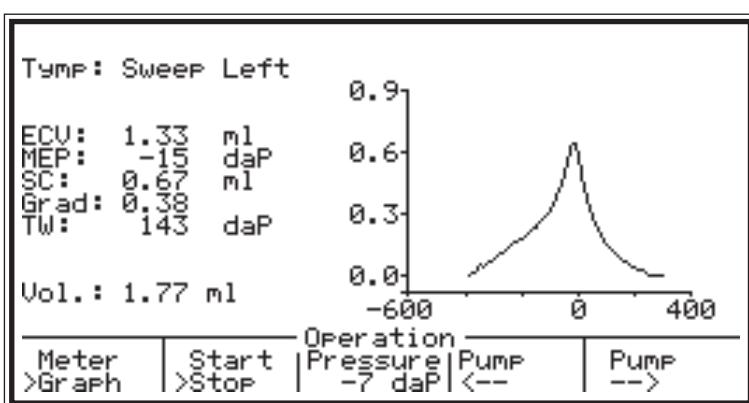
Tymp. Sweep before measurement



hand side of the display (see Fig.4.6). If MEP can be calculated, the pump pressure will now be set at that pressure.

Fig.4.6

Tymp. Sweep after measurement



Definitions of ECV,
MEP, SC, Grad, TW

ECV is recorded at the start of the sweep, i.e. with the maximum pressure when the sweep is in the negative direction, or the minimum pressure when positive sweep has been selected using Setup. MEP is the pump pressure at the peak of the tympanogram, i.e. when the pressures on both surfaces of the eardrum are equal. The Gradient is calculated as follows: static compliance minus the compliance where width = 100 daPa, divided by static compliance [SC – C (width=100daPa) ÷ SC]. TW is the pressure difference between the two points on the curve at which the compliance is half the peak compliance.

Version 4.x Only

The **MEP marker** appears automatically, and is located at the peak of the sweep, i.e. at 0 daP. In cases where it is difficult to carry out a normal sweep and obtain compliance data, e.g. with difficult or unsettled patients, you can manually move the marker in either direction by means of **Softkeys 4 and 5**, and read out the computed values on the left of the display. Note that an asterisk appears to the right of the MEP value if the marker has been moved.

Air Release

To restore the static pressure to zero quickly, press **Air Release**, which automatically resets the pump position.

CAUTION!

Where the patient is already experiencing pain or discomfort, caution should be exercised in selecting pressure range and pump speed, particularly in the positive pressure direction.

In such cases it is better to use Measurement Setup to increase the Min. Pressure and/or reduce the Max. Pressure. Alternatively, change the air pressure manually (§4.1.1).

When starting to test the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will be overwritten. To change to the other ear, press **Alt. Select** and then **Softkey 4**.

Note that the pressure range of -400 to +200 daPa (the factory default) may be expanded to -600 to +400 daPa by pressing **Ext. Range**.

Users who find it more informative to perform tympanometry using analog meters instead of the graphic display of a tympanogram can press **Softkey 1**, and a screen similar to the one shown in Fig.4.7 below will appear.

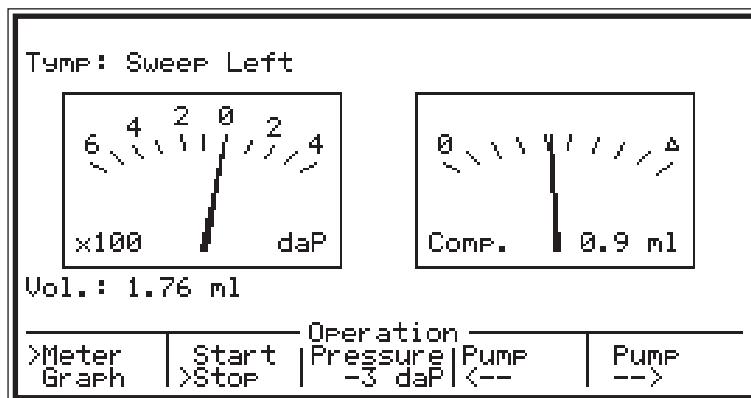


Fig.4.7

Tymp. Sweep analog meter display

Note that pressing **Softkey 1** again after completion of the tymp. measurement will return you to the graphic display and show you the tympanogram you have just made using the analog meters.

The **Alt. Select** pushkey allows you to use the Smooth feature to optimize the curves (see Fig.4.10 below and refer to §4.1.35.1.2 for further details re this function). Just press **Softkey 2** from the Alt. Select sub-menu.

Setup parameters available in Auto Tymp. Mode (see also §5.2.1) are:

Softkey 1

Alt. Select

Setup Parameters

Pump Speed: 50 daPa/S (decaPascals per sec), 100 daPa/S, 200 daPa/S, 400 daP/S, AFAP (AS FAST AS POSSIBLE)

Y-axis Scaling (Compliance): Auto, 0.3 ml, 0.6 ml, 0.9 ml, 1.5 ml, 3.0 ml, 4.5 ml.

Min. Pressure (daPa): -100, -150, -200, -250, -300, -350, -400, -450, -500, -550, -600.

Max. Pressure (daPa): 100, 150, 200, 250, 300, 350, 400.

Measuring Direction: positive, or negative.

Leak Detect: On/Off.

AFAP

When AFAP is selected, the maximum rate of change of pressure varies from 400 daPa/S before and after the peak to 200 daPa/S during the peak. The sweep speed is reduced automatically when the measured parameter is changing rapidly with pressure, and speeded up automatically when the measured parameter is not changing rapidly with pressure. This advanced feature enables the ZODIAC 901 to complete the measurement in the minimum time consistent with achieving the specified accuracy.

NOTE

Note that when AFAP is selected, the measurement sweep stops as soon as a tymp. is detected, thus further abbreviating the duration of the measurement.

Using Setup to reduce the Pressure range can also be beneficial in minimizing the measuring time by eliminating the flat, uninformative parts of the healthy tympanogram.

4.1.3 ETF-I, INTACT EARDRUM

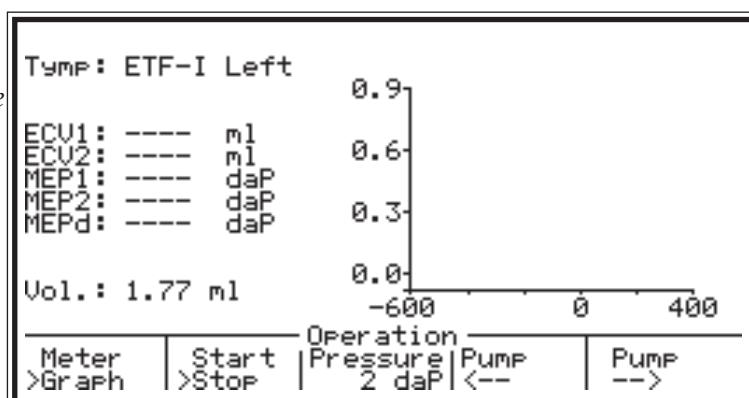
The Eustachian Tube connects the middle ear to the throat, but is normally sealed except during swallowing. Its purpose is to prevent a static pressure differential from building up across the eardrum.

This test is similar to Tymp. Sweep, but provides for a second sweep to be made without erasing the data from the first. The values of Ear Canal Volume (ECV) and Middle Ear Pressure (MEP) from both tests are recorded, and after the second test the difference between the latter, MEPd (= MEP2 minus MEP1), is also computed and displayed (please see Fig.4.8). The MEP marker implemented in Version 4.x, enables the marker for the second sweep to be moved in either direction displaying computed values for MEP2 and MEPd.

*MEP Marker
(Version 4.x Only)*

Fig.4.8

Intact Eardrum, Eustachian Tube Function



The procedure for using the test is to get the patient to try to create an over-pressure in the middle ear by closing the mouth, holding the nose, blowing to create the over-pressure in the throat, and swallowing to open the Eustachian Tube. The patient can then relax while the first sweep is made. Then the patient drinks a glass of water, relieving the over-pressure if the Eustachian Tube Function is normal. The second sweep will then reveal a negative MEP (please see example in Fig.4.9).

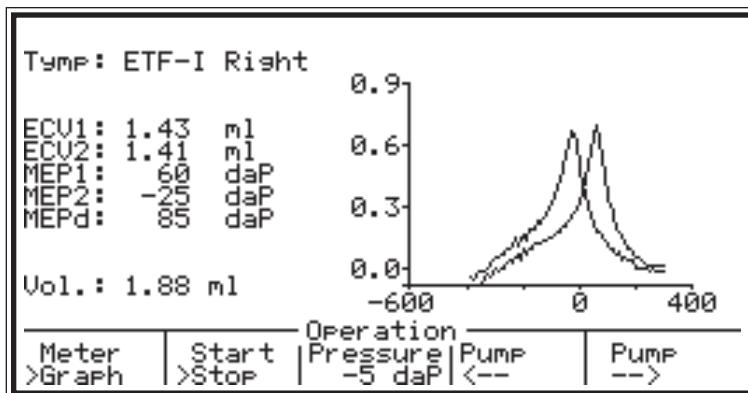


Fig.4.10

Intact Eardrum, Example of Normal Eustachian Tube Function

A closed Eustachian Tube will exhibit the same, positive MEP in both sweeps. A patulous (spread) Eustachian Tube will exhibit an MEP close to zero for both sweeps, and probably a pair of broad, irregular tympanograms as well.

This test is not included in Version 2.x of the ZODIAC 901.

The Intact Eardrum test is included on the Tymp. intermediate menu. Press **Tymp.** to obtain this menu, and then press **Softkey 4** to access the Intact display. The menu functions and Setup parameters are in other respects similar to Tymp. Sweep (§4.1.2).

Softkey 4

Measurement Setup parameters available for the Intact Eardrum test are the same as for Tymp. Auto Sweep (page 35).

The **Alt. Select** pushkey allows you to use the Smooth facility to optimize the curves (see Fig.4.10 below and refer to §4.1.35.1.2 for further details re this function). Just press **Softkey 2** from the Alt. Select sub-menu.

Alt. Select

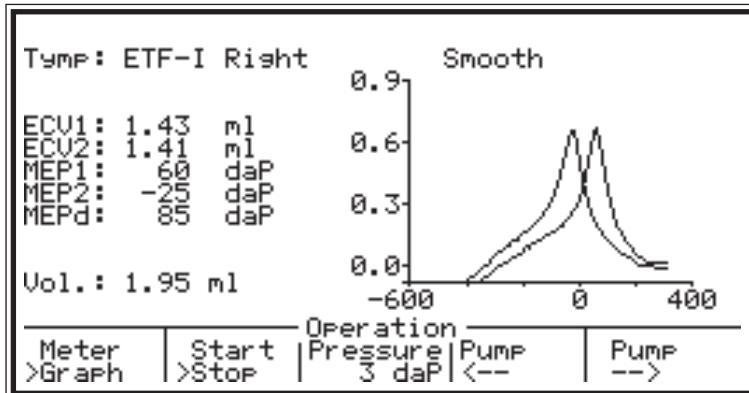


Fig.4.9

As in Fig.4.10 above, but after using the Smooth facility

4.1.4 ETF-P, PERFORATED EARDRUM

In Advanced Mode, the Eustachian Tube Function (ETF-P) test may be performed to test the functioning of the Eustachian Tube in the presence of a perforated eardrum, for example in cases where a pressure differential has been relieved by surgical perforation of the eardrum.

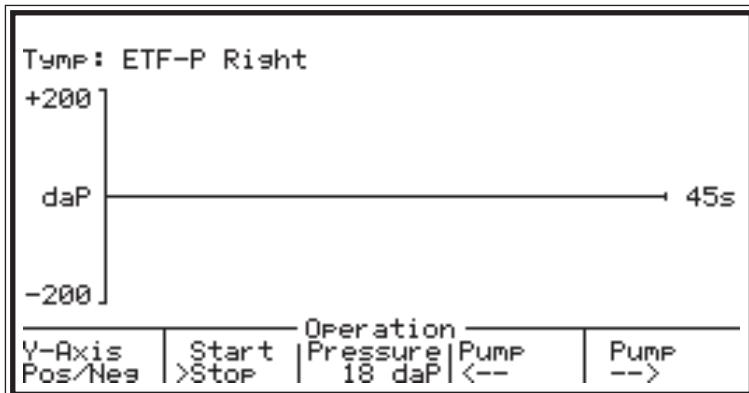
Softkey 5

ETF-P is included on the Tymp. intermediate menu. Press **Tymp.** to obtain this menu, and then press **Softkey 5** to access the ETF-P display (Fig.4.11).

If the default settings have been altered using the ZODICON™ software, the scale of the *x*-axis baseline may differ from the 45 s illustrated, and the *y*-axis may be Pos. only or Neg. only, instead of Pos. and Neg. as shown in Fig.4.11.

Fig.4.11

Eustachian Tube Function,
Perforated Eardrum

**Softkey 4**

Use **Softkey 4** or **Softkey 5** to decrease or increase the pump pressure, respectively. The Status lamp will light while this is being done.

While using the pump, a scale at the top of the display indicates the current pump position graphically, i.e., what proportion of the pump's capacity is used to obtain the static pressure used for the measurement.

Rotary Knob

Alternatively, turn the **Rotary Knob**. The pump position scale will appear temporarily at the top of the display to indicate the pump position graphically.

Softkey 2

Press **Softkey 2** (or the Start/Stop Button on the Probe) to start the test.

Y-Axis

The screen displays the pressure in the ear canal over a 45-second time-base. The patient should be instructed to swallow at regular intervals during the measurement period, if necessary with the help of a glass of water.

Softkey 1

Negative, positive or positive/negative *y*-axis may be selected by means of **Softkey 1**.

Ext. Range

Note that the pressure range of ± 200 daPa may be expanded to ± 400 daPa by pressing **Ext. Range**.

"Staircase" Curve

Each time the patient swallows, a perforated eardrum and a healthy Eustachian Tube will result in a fall in pressure indicated on the display, creating a so-called "staircase" curve after a number of swallows (illustrated in Fig.4.12). This is because the pressure in the ear canal is relieved gradually, via the perforation and the Eustachian Tube. Neither a blocked Eustachian Tube nor an intact eardrum allow relief from the

artificially-created pressure differential, and this will be indicated by the absence of a "staircase".

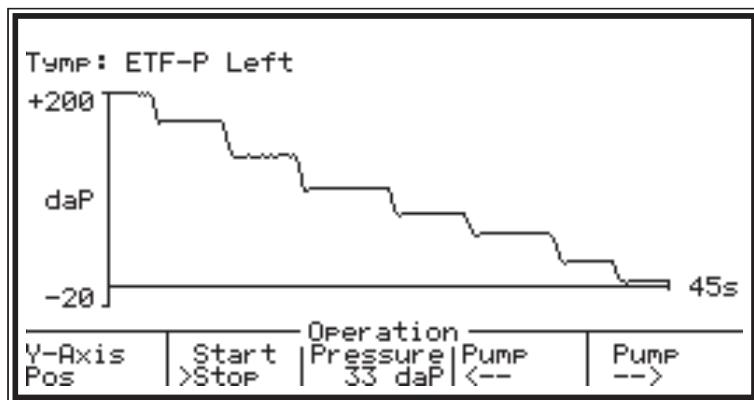


Fig.4.13

Eustachian Tube Function,
Perforated Eardrum

Steady pressure, on the other hand, indicates a blockage in the Eustachian Tube. Impaired Eustachian Tube function will be indicated by reduced pressure drops.

When starting to test the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will be overwritten. To change to the other ear, press **Alt. Select** and then **Softkey 4**.

*Impaired Eustachian
Tube Function*

L/R Shift

4.2 REFLEX TESTING

"Reflex testing" in audiology refers to the Stapedius Reflex, a mechanism which automatically tensions both eardrums after the onset of particularly loud sounds, in order to prevent overload and possible damage to the hearing mechanism. The ZODIAC 901 allows a very wide range of measurements of patients' Reflexes to be performed by applying a controlled acoustic stimulus and measuring the change in acoustic impedance which will be observed if the ear is healthy.

The change in Compliance which results from the functioning of the reflex mechanism is very small, and will be further diminished if the eardrum is tensioned by a static pressure differential between the ear canal and the middle ear. If there is any doubt about whether the Middle-Ear Pressure is close to atmospheric pressure, this should be checked first of all by means of a tympanometry measurement. The Setup facility for reflex and threshold testing allows the ZODIAC 901 to set the static pressure in the ear canal automatically to a level related to a previously measured value of Middle Ear Pressure.

In automatic reflex testing, the Status lamp on the front panel flashes green until a compliance is detected, whereupon it lights steady green. The Stimulus lamp then lights during the application of the stimulus. If there is too much noise, the Status lamp lights red and

Leak Detect On/Off

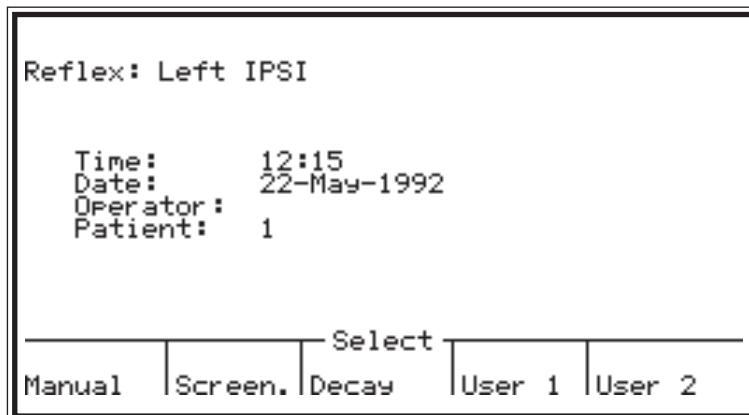
the Leak lamp lights yellow: the measurement is then automatically repeated. If a small leak is detected, the Leak lamp lights yellow and the measurement continues. However, if a leak greater than 20 daPa is detected, the measurement will be repeated. (In Version 4.x, this repeated sweep can be disabled if Leak Detect under Setup is Off).

Reflex

If Advanced Mode has been selected, pressing **Reflex** displays the screen shown in Fig.4.14.

Fig.4.14

Reflex sub-menu obtained when Reflex is selected in Advanced Mode

*User 1 / User 2*

The following operation modes may be selected from the Reflex Menu: Manual, Screening, Decay, User 1 and User 2. Screening is used to test a succession of patients rapidly, to identify those whose reflex reveal middle-ear disorders. The Reflex Decay test is used to examine patients whose Stapedius muscle is unable to maintain a response to sustained loud sounds. User 1 and User 2 are special versions of Reflex Decay tests, in which many of the measurement parameters may be pre-programmed to suit the requirements of the user.

If Easy Mode has been selected, pressing **Reflex** displays the Manual Reflex screen illustrated in Fig.4.15 (unless this has been altered using the ZODICON™ software).

If the default has been modified using the ZODICON™ software, the following default settings may differ from those shown in the Reflex screens illustrated or referred to in the explanations: y-axis scaling and origin position, Pressure Control (MEP), attenuator increment, use of threshold level in decay, Reflex fast/slow mode, threshold level increment, threshold fast screening maximum measure, and use of pump in threshold air conduction.

Two markers (fixed cursors) may be applied to all reflex records. For a description of the marker function, see §4.2.5.

4.2.1 MANUAL REFLEX

Softkey 1

Press **Reflex**, and then **Softkey 1** if Advanced Mode has been selected, to access the Manual Reflex screen for manual testing (Fig.4.15). The manual test mode permits the duration of the stimulus presentation to be manually controlled via the **Tone Switch**.

In Version 4.x, a new feature has been added as default called "Multi Curves"; this function can be (de)selected by pressing **Setup**, **More** and then **Softkey 1**. In addition, the default duration (x-axis) has been extended to 24 seconds. Multiple reflexes can be obtained at different levels for each frequency, and each reflex curve can be individually erased by means of the **Marker Function** (§5.1.6).

Multi Curves

If the default has been modified using the ZODICON™ software, the following default settings may differ from those indicated in this section: stimulus frequency and level, choice of ear, graph/meter, Ipsi/Contra, x-axis scale, pre-stimulus delay time, and post-stimulus display time.

The test is started by pressing the **Tone Switch**, and terminated by releasing it. When performing "Multi Curves", a stimulus is presented each time you press and hold down the **Tone Switch**.

Tone Switch

Press **Softkey 1** to set the desired stimulus type (500, 1000, 2000, 4000 Hz tone or White Noise—note that White Noise is only available if Contra has already been selected).

Softkey 1

Multi Curves: Note that all reflexes made at each frequency are retained in memory until a new patient is selected!

Softkey 2 changes the display from graphic to analog meter format.

Softkey 2

Softkey 3 increases the stimulus Sound Pressure Level, in increments of 5 dB (increments of 1, 2 and 10 dB are available via **Setup**); alternatively, use the **Rotary Knob** to increase or reduce SPL (HL). Range of 50 to 100 dB SPL (HL) may be extended by pressing the **Ext. Range** button to 115 dB (120 dB in Contra).

Softkey 3

Softkey 4 allows the selection of either Ipsi or Contra.

Softkey 4

Pressing **Softkey 5** displays the pump position graphically at the top of the screen and, when **Softkey 5** is held down, the **Rotary Knob** may be used to adjust the pressure. In analog meter format, the right-hand meter displays Volume instead of Compliance while **Softkey 5** is held down.

Softkey 5

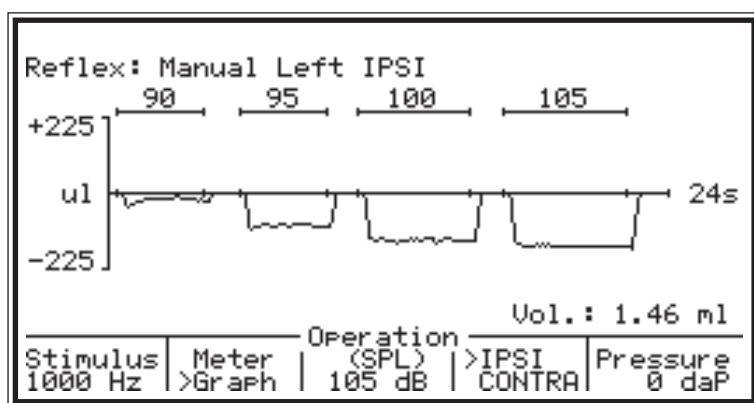


Fig.4.15

Reflex Manual

The second line of the display shows the type and level of stimulus used in the test recorded in the curve.

L/R Shift

When starting to test the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will be overwritten. To change to the other ear, press **Alt. Select** and then **Softkey 4**.

Setup Parameters

Setup parameters available in Manual Reflex Mode (see also §5.2.2) are:

Stimulus Step: 1, 2, 5 or 10 dB

Y-axis scaling: Auto, 75, 150, 225, 300, 375 μ l

Speed: slow or fast

Y-Axis: Auto, negative, positive, positive/negative

Multi Curves

4.2.2 SCREENING

Leak

If there is a leak during the measurement, the **Leak** lights on the front panel and the probe LED will light yellow. Before proceeding, ensure that you are using the right size eartip, and try pulling down the ear lobe while at the same time rotating the eartip in the ear canal. The instrument will continue the procedure automatically unless a leak of more than 18 daPa is encountered. The Status LED will light red and you will hear a beep. If Leak Detect has been disabled (Version 4.x only), the **Leak** lights on the front panel but the analyzer will continue until the end of the measurement, assuming that a volume is present (see Setup, §5.2.1).

Leak Detect On/Off**Version 3.x and Later**

It is worth noting that in Version 3.x and later, a leak encountered after the measurement begins provokes a beep and the **Leak** lights go yellow.

Softkey 2

Ensure that you are in Advanced Mode: press **Main Menu** and use **Softkey 5** to select Advanced Mode (unless this requirement has been changed using the ZODICON™ software). Press **Reflex** to display the Reflex Menu. Press **Softkey 2** from the Reflex Menu to select Reflex Screening.

Select stimulus frequency and intensity, Ipsi or Contra, as desired.

Press **Softkey 2** (or the **Start** key on the Probe) to start the test. Two reflex measurements will be made one after the other (baseline 0.5 sec, stimulus 2 sec, and baseline 0.5 sec, unless these have been modified using the ZODICON™ software). The **Stimulus** lamp on the front panel will light while the stimulus is being applied. The **Status** lamp will light throughout the measurement period.

Tone Switch

Alternatively, press the **Tone Switch** to start the test and only one reflex measurement will be made. If required, change frequency or intensity and press the **Tone Switch** again; another reflex measurement will be made.

After the measurements, the screen will look like the one shown in Fig.4.16.

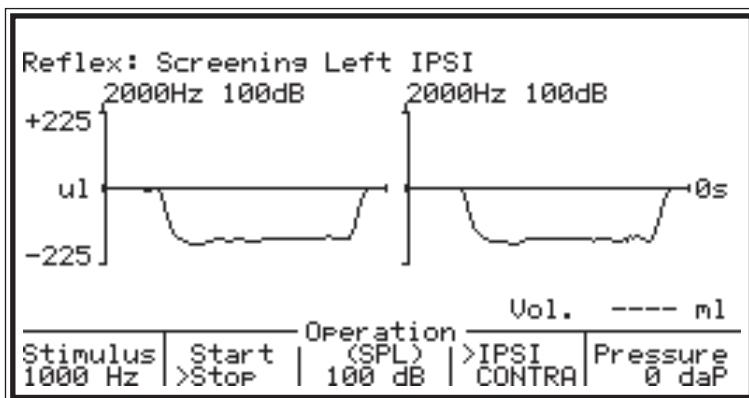


Fig.4.16
Reflex Screening

The **Softkeys** and the **Ext. Range** button function just as described above in §4.2.1, with the exception of **Softkey 2**, which is used for starting and stopping the test—there is no meter display in this operation mode. The test may also be started by the pushbutton on the probe.

Softkey 2

When starting to test the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will be overwritten. To change to the other ear, press **Alt. Select** and then **Softkey 4**.

L/R Shift

Setup parameters available in Screening Reflex Mode (see also §5.2.2) are:

Setup Parameters

Stimulus SPL (HL) increment: 1, 2, 5 or 10 dB
Y-Axis: scaling: Auto, 75, 150, 225, 300, 375 μl
Speed: slow or fast
Y-Axis: Auto, negative, positive, positive/negative
Use Middle Ear Pressure: on or off*
Leak Detect On/Off.

*In Version 3.x and later, this function is called Press.C. (Pressure Control) and is extended to: Manual, Auto, MEP +0, +5, +10, +15, +20, +25, -25, -20, -15, -10, -5 daPa.

4.2.3 DECAY

A weak Stapedius Muscle is unable to sustain tension in the eardrum during the prolonged application of a sound loud enough to provoke Reflex. This test measures a reflex on a 12-second time scale (baseline 1 sec, stimulus 10 sec, and 1 second of recovery time, unless these have been modified using the ZODICON™ software) and can be used to record the decay caused by a weakening Stapedius Muscle.

Decay

Curve For Each Frequency

In Version 3.x and later, this test has been expanded so that the curve for each frequency measured (Ipsi and Contra, for both ears) may be stored and subsequently printed out.

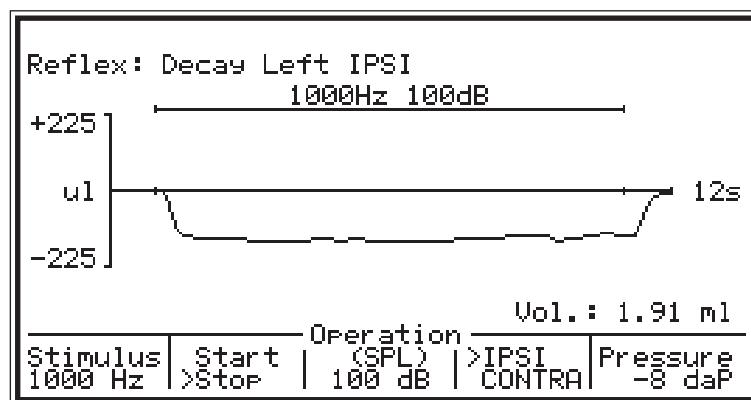
Press **Main Menu** and use **Softkey 5** to select Advanced Mode (unless this requirement has been changed using the ZODICON™ software). Press **Reflex** to display the Reflex Menu.

Softkey 3

Press **Softkey 3** from the Reflex Menu to select Decay, and then press **Softkey 2**, or the **Tone Switch**, or the start button on the probe, to start the test. The screen shown in Fig.4.17 will be displayed (the curve in this illustration is typical of a normal ear).

Fig.4.17

Reflex Decay



Softkey 1

Press **Softkey 1** to set the desired stimulus type (500, 1000, 2000, 4000 Hz or White Noise—note that White Noise is only available if Contra has already been selected.

Softkey 2

Softkey 2 starts or stops the test.

Softkey 3

Softkey 3 increases the intensity in increments of 5 dB (increments of 1, 2 and 10 dB are available via **Setup**); alternatively, use the **Rotary Knob** to increase or reduce stimulus intensity.

Ext. Range

The intensity range of 50 to 105 dB may be extended by pressing the **Ext.Range** button to 115 dB (or to 120 dB in Contra).

Softkey 4

Softkey 4 allows the selection of either Ipsi or Contra.

Softkey 5

Pressing **Softkey 5** displays the pump position graphically at the top of the screen and enables you to adjust the pressure with the **Rotary Knob** as long as **Softkey 5** is kept pressed. When **Softkey 5** is released, the pump-position scale disappears and the **Rotary Knob** reverts to controlling intensity. Note that, if the MEP function has been selected in Measurement Setup, the pressure will be automatically changed by the selected level before the reflex measurement is started.

L/R Shift

When starting to test the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will

be overwritten. To change to the other ear, press **Alt. Select** and then **Softkey 4**.

Setup parameters available in Reflex Decay Mode (see also §5.2.2):

Setup Parameters

Stimulus increment: 1, 2, 5 or 10 dB
Use Threshold: 0, 5, 10, 15 or 20 dB above, or off
Y-axis scaling: Auto, 75, 150, 225, 300, 375 µl
Y-Axis: Auto, negative, positive, positive/negative
Use Middle Ear Pressure: on or off*
Leak Detect: On/Off.

*In Version 3.x and later, this function is called Press.C. (Pressure Control) and is extended to: Manual, Auto, MEP +0, +5, +10, +15, +20, +25, -25, -20, -15, -10, -5 daPa.

4.2.4 USER 1 / USER 2

These tests can be programmed from an external PC via the instrument's RS-232C data interface and with the help of Madsen's ZODICON™ configuration program (see also §6.2). ZODICON™ may be used to customize the ZODIAC 901 for individual preferences. Please refer any inquiry about these facilities to your local distributor. The User 1 and User 2 tests are similar to Reflex Screening, except that there is only one reflex measurement made, and each test allows the *x*-axis duration, pre-stimulation delay, stimulus duration, and post-stimulation record duration, to be separately pre-programmed.

User 1 / User 2

4.2.5 MARKER FUNCTION

All reflex and reflex threshold testing modes have a marker function for the purpose of accurately measuring the duration and degree of an elicited reflex. The marker function may be used to measure Acoustic Reflex Latency, which is the delay of the onset of the reflex from the instant when the stimulus is initiated. This function also enables the deletion of a single curve (also when multiple reflex curves have been obtained at different levels in Manual Reflex, each reflex curve can be individually erased—see §5.1.6).

Acoustic Reflex Latency

The marker is accessed by pressing the **Alt. Select** button from any reflex test mode, and then **Softkey 2** to activate the Marker Mode.

Delete Curves in Manual Reflex

Pressing **Softkey 2** then toggles between Track, Marker 1 and Marker 2, where Track means that both markers move simultaneously. The screen in Fig.4.18 shows Marker 1 and Marker 2 set. The markers are moved by turning the rotary knob.

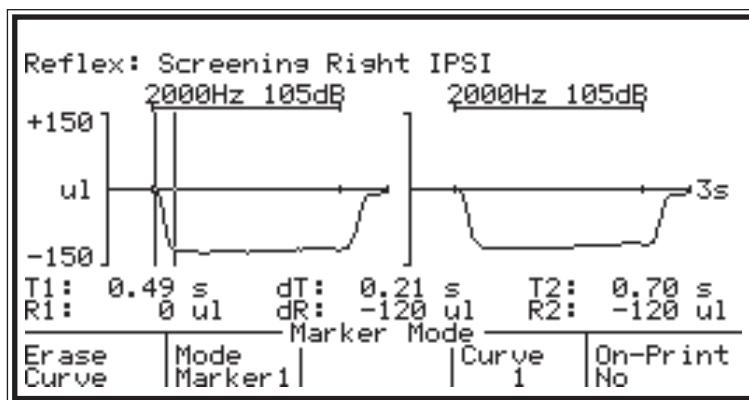
Softkey 2

When the Marker Mode is selected, the following data is displayed between the graphics and the sub-menu lines:

Softkey 2

T1: time elapsed from measuring start for Marker 1.
 T2: time elapsed from measuring start for Marker 2.

Fig.4.1



R1: size of reflex in microliters for Marker 1.
 R2: size of reflex in microliters for Marker 2.

dT: difference in elapsed time between the markers in 1/100ths sec.
 dR: difference in size of reflex between the two markers in μl .

Softkey 4

Softkey 4 enables you to move the marker from the first curve to other reflex curves in all reflex modes where there are more than one.

Softkey 1

Softkey 1 (Erase Curve) enables you to erase any individual curve: first select curve by using **Softkey 4** and the marker, then press **Softkey 1** to erase curve. In Manual Reflex, if you have made multiple curves, select curve(s) by placing Marker 1 to the left of the curve(s) you want to erase, and Marker 2 to the right of the curve(s). Then press **Softkey 1** (Erase Curve).

Softkey 5

In all reflex modes with the exception of Fast Screening, **Softkey 5** enables you to select whether the marker(s) will be included on the print-out or not.

4.3 THRESHOLD TESTING**Threshold**

If Advanced Mode has been selected, pressing **Threshold** displays the screen shown on the next page in Fig.4.19.

The following operation modes may be selected from the Threshold Menu: Reflex Threshold, Fast Screening and Air Conduction. If Easy Mode has been selected, pressing **Threshold** displays the Threshold Fast Screening test illustrated in Fig. 4.20 (unless programmed otherwise by means of ZODICON™).

If the factory default settings have been modified using the ZODICON™ software, the following defaults may differ from those indicated below: threshold level increment, threshold fast screening maximum number of

measurements, *x*-axis, pre-stimulation delay, stimulation duration, and post-stimulation delay.

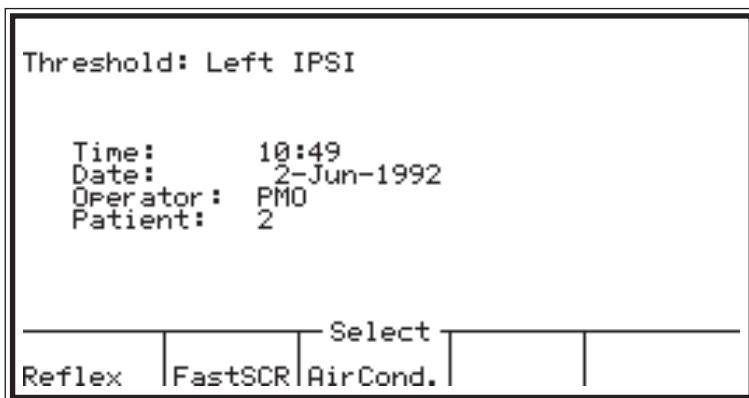


Fig.4.19

Threshold sub-menu displayed when Threshold is selected in Advanced Mode

The Threshold Detect Delta Volume and Threshold Detection Time (duration of delta compliance after the onset of a stimulus) are set at the factory to 20 μ l and 500 msec, respectively. Smaller changes in volume, or changes occurring after this time, will be registered as N/R (No Reflex). These measurement parameters may also be altered using the ZODICON™ software.

Threshold Detection

In Version 3.x and later, threshold detection may also be programmed to only accept negative reflexes, by means of ZODICON™. Two markers (fixed cursors) may be applied to all reflex threshold records. For a description of the marker function, see §4.2.5.

4.3.1 THRESHOLD REFLEX

This test mode permits automatic Threshold Reflex search at six different levels. Once a reflex has been found, the test stops. It may be continued manually (i.e., a further test at a higher or lower level may be made), by pressing the Tone Switch. If Additional Threshold has been selected under Setup (§5.2.3), one additional measurement will automatically be run (at the same level, or +5 dB, or +10 dB). Data from all stimulus frequencies (500, 1000, 2000, 4000Hz, White Noise, if Contra has already been selected) is memorized.

Reflex

*Add. Threshold
(Version 4.x)*

Press **Threshold**, or **Softkey 1** from the Threshold Menu if Advanced Mode has been selected, to access the screen shown in Fig.4.20. Note that, in Easy Mode, pressing Threshold might access one of the other Threshold measurement modes if the instrument has been programmed by means of the ZODICON™ software.

Softkey 1

Press **Softkey 1** to set the desired stimulus (500, 1000, 2000, 4000 Hz or White Noise—note that White Noise is only available if Contra has already been selected).

Softkey 1

Softkey 2 starts or stops the test. The pushkey on the probe may also be used to do this.

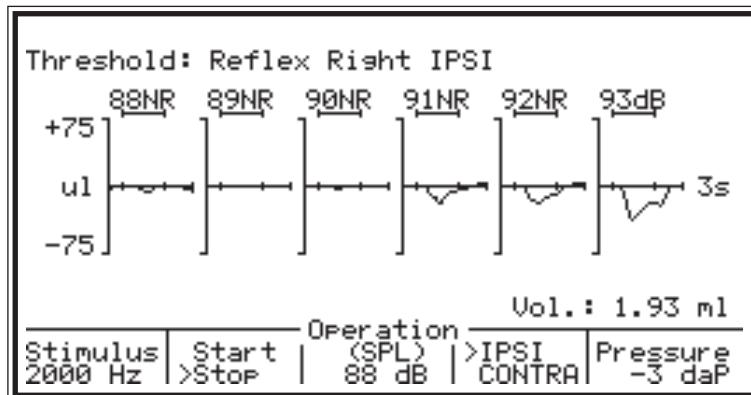
Softkey 2

Tone Switch

Alternatively, press the **Tone Switch** to start the test and only one curve will be made. If required, change frequency or intensity and press the **Tone Switch** again; another curve will be made.

Fig.4.20

Threshold Reflex

**Softkey 3**

Softkey 3 increases the Sound Pressure Level in increments of 5 dB (increments of 1, 2 and 10 dB are available via **Setup**); alternatively, use the **Rotary Knob** to increase or reduce intensity level.

Ext. Range

Range of 50 to 105 dB may be extended by pressing the **Ext. Range** button to 115 dB (120 dB in Contra).

Softkey 4

Softkey 4 allows the selection of either Ipsi or Contra.

Softkey 5

Pressing **Softkey 5** displays the pump position graphically at the top of the screen and enables you to adjust the pressure with the **Rotary Knob** as long as **Softkey 5** is kept pressed. The graphic scale shows how much of the pump capacity is used to obtain the pressure shown. When **Softkey 5** is released, the scale is removed and turning the **Rotary Knob** reverts to controlling intensity. Note that, if the MEP function has been selected in Measurement Setup, the pressure will be automatically changed by the selected level before the reflex measurement is started.

L/R Shift

When starting to test the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will be overwritten. To change to the other ear, press **Alt. Select** and then **Softkey 4**.

Setup Parameters

Setup parameters available in Reflex Threshold Mode (see also §5.2.3.1) are:

Stimulus increment: 1, 2, 5 or 10 dB
TH Step: 1, 2, 5, 10, 20, -20, -10, -5, -2, -1 dB
Y-axis scaling: Auto, 75, 150, 225, 300, 375 µl
Y-Axis: Auto, negative, positive, positive/negative
Use Middle Ear Pressure: on or off*
Leak Detect: On/Off.
Add. Threshold: None, 0, 5, 10 dB

*In Version 3.x and later, this function is called Press.C. (Pressure Control) and is extended to: Manual, Auto, MEP +0, +5, +10, +15, +20, +25, -25, -20, -15, -10, -5 daPa.

4.3.2 FAST SCREENING

This test mode permits automatic reflex threshold search at up to 16 different levels. Data from all stimulus frequencies (500, 1000, 2000 and 4000 Hz tone, plus White Noise if Contra has already been selected) is memorized and displayed in tabular form on the right of the screen. The display is organized very differently from that used for Threshold Reflex (see §4.3.1). If the default has been modified using ZODICON™ software, the *x*-axis, pre-stimulation delay, stimulation time and post-stimulation delay may be different from those indicated.

NOTE that it is not possible to export any graphic data from this test mode, i.e. only measured threshold values may be printed out or transmitted via the data interface.

Reflex

NOTE

Press **Main Menu** and use **Softkey 5** to select Advanced Mode. Press **Threshold** to display the Threshold Menu. Press **Softkey 2** from the Threshold Menu to access the screen shown in Fig.4.21.

Softkey 2

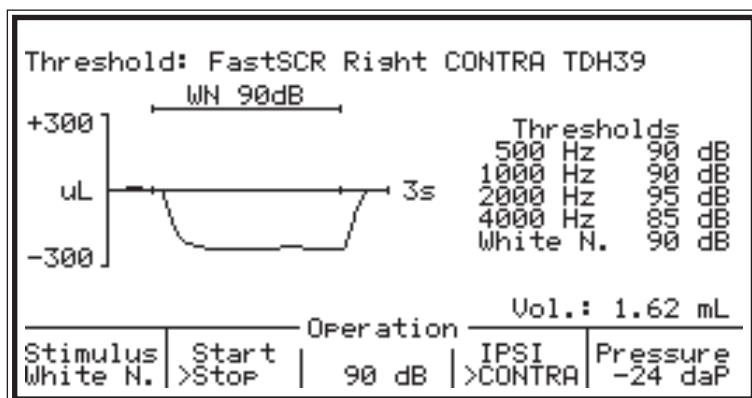


Fig.4.21

Threshold Fast Screening

Note that, when Contra is selected, the type of phone is displayed as well as White Noise stimulus, if selected.

Contra

Press **Softkey 1** to set the desired stimulus type. Press it repeatedly, or keep it pressed and turn the **Rotary Knob** left or right. The stimuli available are: tone at 500, 1000, 2000, and 4000 Hz, plus White Noise if Contra has been selected.

Softkey 1

Softkey 2 starts or stops the test. The pushkey on the probe may also be used to do this. The ZODIAC 901 will conduct three tests automatically using the elected stimulus at 70 dB, 80 dB and 90 dB in turn. If it finds a reflex, it will show its threshold level in the panel in the right-hand part of the display, and stop further testing. If not, it will display NR (= No Reflex). The number of tests conducted in turn, the step size from each step to the next, etc., may be changed using Setup. The tests may be repeated with each of the available stimuli in turn.

Softkey 2

Tone Switch

Alternatively, press the **Tone Switch** to start the test and only one reflex measurement will be made. If required, change frequency or intensity and press the **Tone Switch** again; another reflex measurement will be made.

Softkey 3

Softkey 3 increases the Sound Pressure Level in increments of 5 dB (increments of 1, 2 and 10 dB are available via **Setup**); alternatively, use the **Rotary Knob** to increase or reduce intensity level.

Ext. Range

The range of 50 to 105 dB may be extended by pressing the **Ext. Range** button to 115 dB in Ipsi and to 120 dB in Contra.

Softkey 4

Softkey 4 allows the selection of either Ipsi or Contra.

Softkey 5

Pressing **Softkey 5** displays the pump position graphically at the top of the screen and allows you to adjust the pressure with the **Rotary Knob** as long as **Softkey 5** is kept pressed. The graphic scale shows how much of the pump capacity is used to obtain the pressure shown. When **Softkey 5** is released, the scale is removed and turning the **Rotary Knob** reverts to controlling intensity. Note that, if the MEP function has been selected in Measurement Setup, the pressure will be automatically changed by the selected level before the reflex measurement is started.

The ear canal pressure may also be set to be automatically equal to the previously measured value of Middle Ear Pressure (MEP), using Setup (§5.2.3.2).

L/R Shift

When starting to test the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will be overwritten. To change to the other ear, press **Alt. Select** and then **Softkey 4**.

Setup Parameters

Setup parameters available in Fast Screening Threshold Mode (see also §5.2.3.2) are:

Stimulus increment: 1, 2, 5 or 10 dB
TH Step: 1, 2, 5, 10, 20, -20, -10, -5, -2, -1 dB
Max. no. of Measurements: 1 to 16
Y-Axis: Auto, negative, positive, positive/negative
Use Middle Ear Pressure: on or off*
Leak Detect: On/Off.

*In Version 3.x and later, this function is called Press.C. (Pressure Control) and is extended to: Manual, Auto, MEP +0, +5, +10, +15, +20, +25, -25, -20, -15, -10, -5 daPa.

4.3.3 AIR CONDUCTION

This test mode enables the operator to use TDH 39 contra headphones for determining air conduction thresholds. It also allows a bone-conductor to be used for performing Gellé's test, to investigate the mobility of the ossicles, and especially of the stapes.

Press **Main Menu** and use **Softkey 5** to select Advanced Mode. Press **Threshold** to display the Threshold Menu. Press **Softkey 3** from the Threshold Menu to access the screen shown in Fig.4.22.

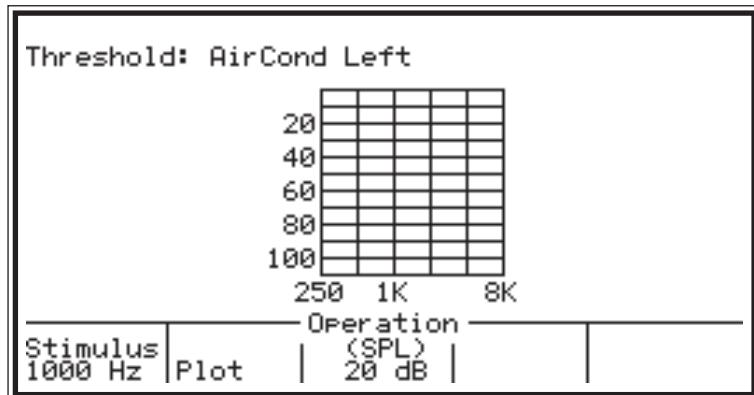


Fig.4.22

Air Conduction Threshold before measurement

Press the **Tone Switch** to present the stimulus.

Tone Switch

The threshold values may be plotted on an audiogram on the display—just select frequency using **Softkey 1** and Sound Pressure Level in dB using **Softkey 3** or the **Rotary Knob**.

Softkeys 1 / 3

The range 0–100 dB may be extended by pressing the **Ext. Range** button to 120 dB.

Ext. Range

Press **Softkey 2** to plot each threshold on the audiogram. Any values may be entered; Fig.4.23 shows an example.

Softkey 2

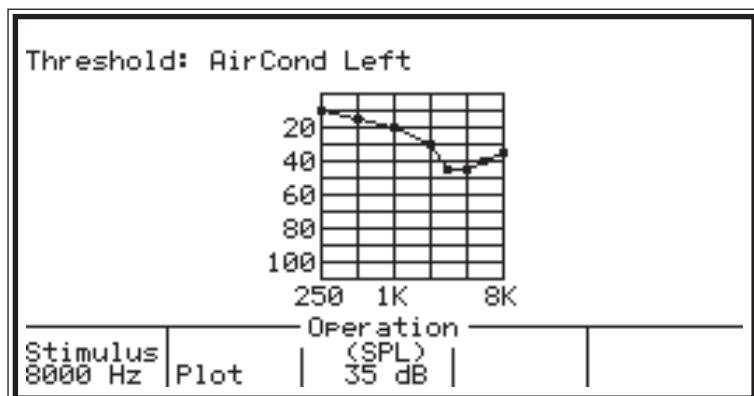


Fig.4.23

Air Conduction Threshold after measurement

When starting to test the patient's other ear, remember to register the change-over on the ZODIAC 901, otherwise the data for the first ear will be overwritten. To change to the other ear, press **Alt. Select** and then **Softkey 4**.

L/R Shift

Setup Parameters

Setup parameters available in the Air Conduction Threshold Mode (see also §5.2.3.3) are:

Intensity Level increment: 1, 2, 5 or 10 dB
Pump: on or off

Pump On

If the pump is on, pump pressure can be increased or decreased manually by holding down **Softkey 5** and turning the rotary knob to the left or right. Pressure in daPa can be read out from the display.

When the pump is enabled, the pressure range is changed to extended range (-600 daPa to +400 daPa).

Gelle's test

The Air Conduction Threshold mode may also be used to perform Gelle's test, using the probe to apply a static pressure or depression to the ear canal (in Air Conduction Threshold mode there is no probe tone). Remember to disconnect the TDH 39 headphone from the miniature jack in the side of the probe, if connected.

An audiometer is required to perform audiology with bone conduction.

Apply the bone conductor to the patient at the mastoid. Record the patient's audiogram several times with different pump pressures. Lack of variation of threshold between the different audiograms indicates a probable fixation of the *stapes*.

5. SUPPLEMENTARY FUNCTIONS

5.1 ALT. SELECT

As described previously (§3.2.4), the **Alt. Select** pushbutton offers an additional sub-menu, which appears on the display in place of the submenu of whichever test mode is operational at the time.

Additional Sub-Menu

The **Alt. Select** pushbutton accesses the following functions at any time (except when a test is in progress): Erase Data, Smooth (not Version 2.x of the ZODIAC 901), Marker, Data Xmit, L/R (shift from one ear to the other), Contrast (for adjusting the display's contrast). Afterwards, press **Alt. Select** again to return to the function currently selected.

Alt. Select

5.1.1 ERASE DATA

This function appears on the display only if there are any data for your patient in the current test.

Only data for the current ear and the current test are erased (e.g. a tympanogram). In Reflex Decay and Reflex Threshold, all measured curves in that test for the current ear in either Ipsi or Contra (not both) are erased.

Softkey 1

Note that you are given an opportunity to change your mind after pressing **Softkey 1** the first time (Erase Data: Yes, No?).

Please refer to Erase Curve in the Marker Function.

5.1.2 SMOOTH

The Smooth facility may be used to electronically clean up tympanograms and any other Cartesian graphs recorded for the current patient in the event of irregularities caused by, for example, a fidgety child or a patulous Eustachian Tube. The facility is not included in earlier versions of the ZODIAC 901.

Softkey 2

This facility is only available in the following test modes: Manual Tymp., Auto Tymp. Sweep, and ETF-I.

5.1.3 DATA TRANSMIT

ZODIAC 901 is supplied with an RS-232C data interface as standard. However, it should be noted that data transfer, in fact any form of communication with a PC, is possible only if your PC has been

Zodi-Link for NOAH

installed with suitable software. For this purpose, Madsen Electronics supplies the MateBaseTM dedicated software for the transfer and storage of audiological test results and patient data (supplied as standard with the ZODIAC 901 and MIDIMATE 622). Zodi-LinkTM software is also available for transferring data to NOAHTTM.

DataXmit implements an internal flag which can be read by an external application program and data transfer can then be executed.

5.1.4 LEFT/RIGHT SHIFT

Softkey 4

Pressing **Softkey 4**, L/R, switches from one ear to the other—all data on the other ear are already stored in memory.

5.1.5 CONTRAST

To Adjust Contrast

The contrast on ZODIAC's Liquid Crystal Display (LCD) may be adjusted, either from Setup (see §7.2) or from the Alt. Select Menu.

After accessing the Alt. Select Menu, note that there is a number displayed on the lower line, under the word "Contrast".

Softkey 5

Hold down **Softkey 5** and turn the **Rotary Knob**—turning it clockwise increases the number and the contrast, while turning it anti-clockwise reduces the number and the contrast.

Adjust the contrast according to personal preference or lighting conditions.

Your contrast adjustment is stored in the instrument's non-volatile memory, which means that it will retain this setting after power-off, and until the next adjustment.

5.1.6 MARKER

In the different test modes, the marker function is available for accurately reading out test data. Typically, the marker(s) are moved by means of pressing one of the softkeys, or by pressing Alt. Select and using the **Rotary Knob**. In tympanometry, Tymp Sweep and ETF-I modes have a marker function for automatic indication of MEP (Version 4.x only).

All reflex and reflex threshold testing modes have a marker function for the purpose of accurately measuring the duration and degree of an elicited reflex. The marker function may be used to measure Acoustic Reflex Latency, which is the delay of the onset of the reflex from the instant when the stimulus is initiated. This function also enables the deletion of a single curve.

From Version 4.x of the ZODIAC 901 (including the Limited Version), a Middle-Ear Pressure (MEP) marker has been implemented in Tymp Auto Sweep and ETF-I testing. Softkeys 4 and 5 no longer are used for moving the pump, but for moving the marker instead. When moving the MEP marker, the current values for MEP, SC, Gradient and TW are displayed in real time on the left of the screen. An asterisk appears to the right of the MEP value to indicate that the marker has been moved.

Version 4.x Only!

*Tympanometry and
ETF-I*

The **MEP marker** appears automatically, and is located at the peak of the sweep, i.e. at 0 daP. In cases where it is difficult to carry out a normal sweep and obtain compliance data, e.g. with difficult or unsettled patients, you can manually move the marker in either direction by means of **Softkeys 4 and 5**, and read out the computed values on the left of the display. Note that an asterisk appears to the right of the MEP value if the marker has been moved.

Auto Tymp Sweep

In the Eustachian Tube Function test for intact eardrum, a second sweep is made without erasing the data from the first. The values of Ear Canal Volume (ECV) and Middle Ear Pressure (MEP) from both tests are recorded, and after the second test the difference between the latter, MEPd (= MEP2 minus MEP1), is also computed and displayed. The MEP marker implemented in Version 4.x, enables the marker for the second sweep to be moved in either direction displaying computed values for MEP2 and MEPd. Softkeys 4 and 5 are used for moving the marker to the left or right.

ETF-I

MEP Marker

Reflex and reflex threshold testing:

The marker is accessed by pressing the **Alt. Select** button from any reflex test mode, and then **Softkey 2** to activate the Marker Mode.

Softkey 2

Pressing **Softkey 2** then toggles between Track, Marker 1 and Marker 2, where Track means that both markers move simultaneously. The screen in Fig. 5.1 shows Marker 1 and Marker 2 set.

Softkey 2

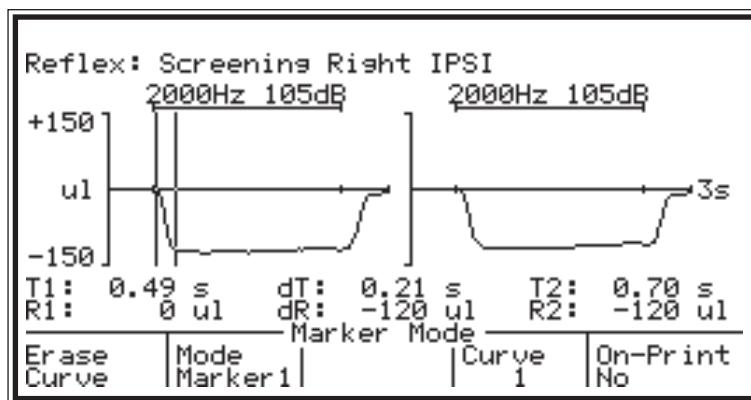


Fig.5.1

Reflex Screening with Marker

The markers are moved by turning the rotary knob.

When the Marker Mode is selected, the following data is displayed between the graphics and the sub-menu lines:

T1: time elapsed from measuring start for Marker 1.
T2: time elapsed from measuring start for Marker 2.

R1: size of reflex in microliters for Marker 1.
R2: size of reflex in microliters for Marker 2.

dT: difference in elapsed time between the two markers in 1/100ths sec.
dR: difference in size of reflex between the two markers in μl .

Softkey 4

Softkey 4 enables you to move the marker from the first curve to other reflex curves in all reflex modes where there are more than one.

Softkey 1

Softkey 1 (Erase Curve) enables you to erase any individual curve: first select curve by using **Softkey 4** and the marker, then press **Softkey 1** to erase curve.

Softkey 5

In all reflex modes with the exception of Fast Screening, **Softkey 5** enables you to select whether the marker(s) will be included on the print-out or not.

5.2 SETUP

Two Kinds Of Setup

ZODIAC 901 has two kinds of setup: one mode for altering test parameters (Measurement Setup), which may be entered by means of the **Setup** pushbutton in the center of the front panel, and one mode (System Setup) for basic instrument functions such as language and clock, which may only be entered by pressing **Setup** when powering on (please refer to §7.2).

Version 4.x Only!

From Version 4.x, additional setup choices have been added to some sub-menus with the result that **Softkey 5, More**, may be used to access these functions.

Setup

As previously stated on page 29, the Setup sub-menus may be accessed from any function or test mode enabling the user to alter many of the test parameters as desired.

Simply press **Setup** to access the appropriate setup sub-menu.

Note that **Setup** may be accessed only from a test mode, and then not during an actual measurement!

From Tymp. Sweep, for example, the Setup sub-menu can be seen in the display illustrated in Fig.5.2.

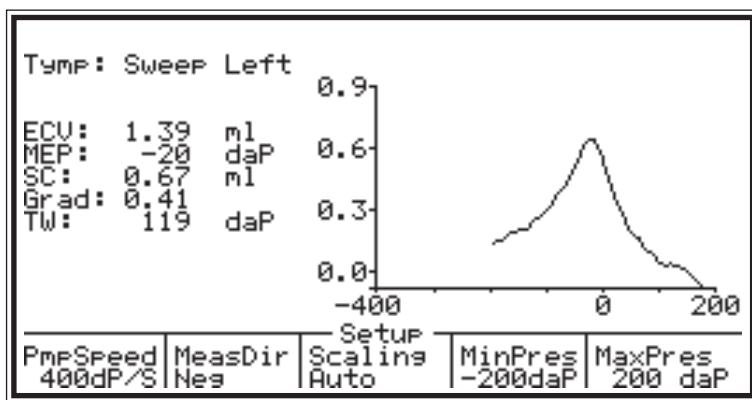


Fig.5.2

Tymp. Sweep Setup

Test parameters that may be altered vary according to which test mode is currently selected: e.g., there is no provision for changing pump speed in reflex measurements, nor for adjusting the y-axis in tympanometry—only relevant parameters may be changed.

To Exit Setup

Setup may be exited simply by pressing the **Setup** pushbutton again.

In Tymp Auto Sweep and ETF-I modes, selecting **More** changes the submenu choices to: optional use of a measurement pressure level a selected interval above or below Middle-Ear Pressure (MEP), and Leak Detect on or off (Version 4.x). Press **Setup** again to return to the function currently selected.

Setup, More (Version 4.x Only)

In Reflex testing, **Setup, More** enables the addition of Leak Detect on or off (Version 4.x).

Here follows an overview of the parameters that may be altered in tympanometry, reflex and threshold test modes. To change any test parameter in Setup, press the corresponding **Softkey** repeatedly until the required choice is shown in the panel above it. Alternatively, hold the corresponding **Softkey** down and turn the **Rotary Knob** (in either direction).

5.2.1 TYMPANOMETRY (INCL. ETF-I)

Pump Speed: The settings available are: 50, 100, 200, 400 daPa/sec and AFAP (as fast as possible). This parameter is not available in Manual Tymp.

Pump Speed

Y-axis Scaling (Compliance): The following settings are available: 0.3, 0.6, 0.9, 1.5, 3.0, 4.5 ml or Auto. In Auto, the minimum possible scaling for the measured curve is automatically selected.

Scaling

Averaging: On/Off (Manual Tymp. only).

Averaging

Min. Pres., Max. Pres.: Minimum Pressure: -100, -150, -200, -250, -300, -350, -400, -450, -500, -550, -600 daPa. Maximum Pressure: 100, 150, 200, 250, 300, 350, 400 daPa.

Min. Pressure, Max. Pressure

This last function is not applicable for Manual Tymp. and may be over-ridden by **Ext. Range**.

<i>Measurement Direction</i>	Measurement Direction:	You may select between negative or positive (and positive/negative in Manual Tymp.).
<i>Leak Detect On/Off</i>	Leak Detect:	On or Off

NOTE **NOTE:** These Setup parameters do not apply to the ETF Perforated Eardrum test.

5.2.2 REFLEX TESTING

<i>Stimulus SPL Increments</i>	Stimulus SPL Increments:	The following settings are available: 1, 2, 5, 10 dB.
<i>Scaling</i>	Y-axis Scaling (Compliance):	Together with the Y-axis parameter, it is possible to select numerous different reflex threshold configurations. Here, it is possible to select 75, 150, 225, 300, 375 μ l of volume, or Auto. If Auto is selected, the instrument will automatically select the volume which displays the measured curve in the greatest detail.
<i>Sweep Speed</i>	Speed:	Display filter speed may be selected as fast or slow: the latter setting gives less noise but is less accurate when measuring reflex latency.
<i>Y-Axis</i>	Y-Axis:	It is possible to select between Pos(itive), Neg(ative), Pos/Neg and Auto. If Auto is selected, the instrument will automatically select whichever Y-axis displays the measured curve in the greatest detail.
<i>Use MEP</i>	Use MEP (Press.C.):	Selects whether automatic adjustment of MEP (middle-ear pressure) is on or off. In Version 3.x, Pressure Control includes: Manual, Auto, MEP+5, +10, +15, +20, +25, -25, -20, -15, -10, -5 daPa. When Auto is selected, an automatic offset to MEP is calculated on the basis of Gradient and TW.
<i>Threshold Level</i>	Use THL:	In the setup for reflex decay, pressing Softkey 2 enables you to select THL (Threshold Level) Off or to present stimulus at a level of 0, 5, 10, 15 or 20 dB above the previously found reflex threshold at any given frequency. If you have measured reflex thresholds using both Reflex Threshold and Fast Screening, the value found

in the former will be automatically used by Reflex Decay.

Multi Curves: In Manual Reflex, select multiple curves or single curve. *Version 4.x Only*

5.2.3 THRESHOLD

5.2.3.1 REFLEX

Stimulus Increments:	The following settings are available: 1, 2, 5, 10 dB (Attenuation Steps).	<i>Stimulus Increments</i>
Y-axis Scaling:	Together with the Y-axis parameter, it is possible to select numerous different reflex threshold configurations. Here, it is possible to select 75, 150, 225, 300, 375 μ l of volume, or Auto. If Auto is selected, the instrument will automatically select the volume which displays the measured curve in the greatest detail.	<i>Scaling</i>
Threshold Step:	The following settings are available: 1, 2, 5, 10, 20, -1, -2, -5, -10, -20 dB	<i>Threshold Step</i>
Y-Axis:	it is possible to select between Pos(itive), Neg(ative), Pos/Neg and Auto. If Auto is selected, the instrument will automatically select whichever Y-axis displays the measured curve in the greatest detail.	<i>Y-Axis</i>
Use MEP (Press.C.):	Selects whether automatic adjustment of MEP (middle-ear pressure) is on or off. In Version 3.x and later, Pressure Control includes: Manual, Auto, MEP+5, +10, +15, +20, +25, -25, -20, -15, -10, -5 daPa. When Auto is selected, an automatic offset to MEP is calculated on the basis of Gradient and TW.	<i>Use MEP</i>
Leak Detect:	On or Off	<i>Leak Detect On/Off</i>
Add. Threshold:	None, 0, 5, 10 dB	<i>Add. Threshold</i>

5.2.3.2 FAST SCREENING

<i>Stimulus Increments</i>	Stimulus Increments:	The following settings are available: 1, 2, 5, 10 dB.
<i>Threshold Step</i>	Threshold Step:	The following settings are available: 1, 2, 5, 10, 20, -1, -2, -5, -10, -20 dB
<i>MaxMeas</i>	MaxMeas:	Selects the maximum number of measurements per frequency from 1 to 16.
<i>Y-Axis</i>	Y-Axis:	it is possible to select between Pos(itive), Neg(ative), Pos/Neg and Auto. If Auto is selected, the instrument will automatically select whichever Y-axis displays the measured curve in the greatest detail.
<i>Use MEP</i>	Use MEP (Press.C.):	Selects whether automatic adjustment of MEP (middle-ear pressure) is on or off. In Version 3.x, Pressure Control includes: Manual, Auto, MEP+5, +10, +15, +20, +25, -25, -20, -15, -10, -5 daPa. When Auto is selected, an automatic offset to MEP is calculated on the basis of Gradient and TW.
<i>Leak Detect On/Off</i>	Leak Detect:	On or Off

5.2.3.3 AIR CONDUCTION

<i>Stimulus Increments</i>	Stimulus Increments:	The following settings are available: 1, 2, 5, 10 dB.
<i>Pump On or Off</i>	Pump:	Switches pump on or off (see Gellé's Test, 4.3.3).

5.3 PRINTER

<i>External Printer</i>	The ZODIAC 901 Middle-Ear Analyzer is equipped with a thermal printer as standard—it may, however, be supplied without the built-in printer. Whether you have a built-in printer or not, your ZODIAC 901 has a parallel port on its rear panel for connection to an external printer. Default installed in ZODIAC 901 is the HP generic Laserjet printer driver which can be used together with any printer where PCL may be selected. A Centronics cable for connection to a printer may be supplied as an optional accessory. Other drivers for external printer may be defined by means of ZODICON™, e.g. Epson FX, HP Deskjet 500 and IBM Proprinter.
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<i>MIDIMATE 622</i>	In addition, ZODIAC 901 may be connected via the RS232C Data Interface serial port to the MIDIMATE 622 Audiometer, to allow the MIDIMATE 622 to print out audiograms on ZODIAC 901's built-in printer or,
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via ZODIAC 901, on an external printer. Please refer to the MIDIMATE 622 Operation Manual for full details.

Pressing Softkey 4 from the Printer Sub-Menu selects whether printer output from ZODIAC goes to an external or to the internal printer.

Softkey 4

Pressing **Printer** displays a screen with the current test (in the screen displayed in , a tympanogram) and the Printer Sub-Menu (the option shown here for Softkey 4 is only available for instruments with built-in printer). §5.3.2 below describes the different options available from the Printer Sub-Menu in detail.

Printer

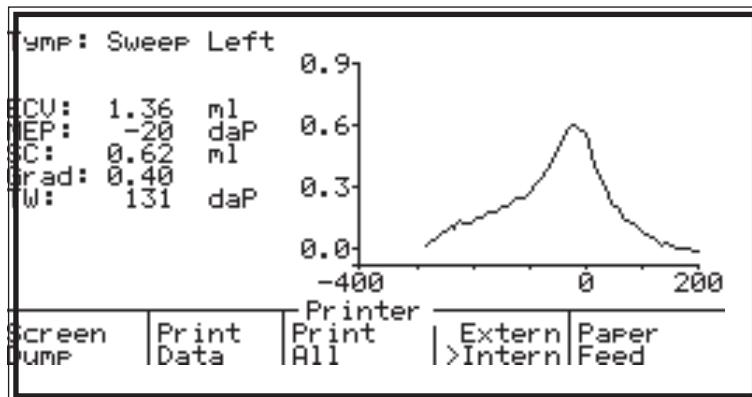


Fig.5.3

Tymp. Sweep Printer menu

5.3.1 PAPER LOADING

Access the printer menu by pressing **Printer**.

Printer

Select internal printer by pressing **Softkey 4** so that paper feed is enabled.

Softkey 4

Using a pair of scissors, cut the leading edge of the paper roll at the right corner so that the leading edge makes a diagonal.

Insert the paper roll into the printer compartment.

With the leading edge at the bottom of the roll, insert the pointed edge into the left-hand corner of the slot inside the printer compartment and press **Softkey 5** for paper feed. The paper will now feed through the printer mechanism and emerge through the slot in the ZODIAC's lid. Put the cover provided for it over the printer compartment. You are now ready to print.

Softkey 5

5.3.2 PRINTOUT

Four different kinds of printout may be made: screen dump, print data on screen only, print all data, or print all new data. "All data" means all data available for both ears, and for all tests made for that patient.

Printer

From Version 4.x, printout may be interrupted. To stop printout when in progress, press and hold down the **Printer** pushbutton until **Cancel** appears over **Softkey 4**.

Softkey 4

Press **Softkey 4** until printout stops.

5.3.2.1 SCREEN DUMP

Softkey 1

Pressing **Softkey 1**, Screen Dump, prints **ALL** data and test results shown on the screen, including the operation commands, etc., in the bottom two lines of the display.

5.3.2.2 PRINT DATA

Softkey 2

Pressing **Softkey 2**, Print Data, only the data and test results for that test are printed out, plus setup parameters not shown on the screen. This means that, in Reflex Decay and Reflex Threshold, all curves for all frequencies are printed out.

For convenience, this choice of printout is distinguished visually from the Screen Dump by the presence of a frame printed around the test title and ear selection (left or right). If there is no test data to print out, the panel offering this function is blank, and **Softkey 2** has no effect.

5.3.2.3 PRINT ALL

Softkey 3

Pressing **Softkey 3**, Print All, not only prints out all test data, for both ears, for the current patient, but also the Madsen Electronics header together with your own, if it has been entered via the ZODICON™ configuration program. The sequence of tests in the printout may also be defined by means of ZODICON™.

Version 4.x Only

Pressing **Softkey 3**, Print All, displays a new sub-menu offering you the choice between printing out all data, as described in the previous paragraph, or printing out only new data, i.e. data gathered from measurements made since the last Print All.

6. AUTO MODE

The ZODIAC 901 not only has the capability for manual and automatic middle-ear testing but also has the unique capacity to run a sequence of tests, set up for the operator's own convenience and according to his/her preferences (see User Test Programming in §7.1). Up to four of these sequences may be programmed and they may also include pauses, printouts, in fact anything that you can do in Manual Mode!

In addition, the instrument leaves the factory with five Madsen Electronics Preset tests, which may not be altered.

The ZODIAC 901 can be user-programmed so that all the measurements required are remotely controlled from the Stop/Start pushbutton on the Probe, without the need to touch the front panel controls. This feature may be used to speed up the screening of large numbers of patients.

The top line of the LCD will display "AUTOMATIC MODE" when the ZODIAC 901 is in Auto Mode, regardless of the function it is performing. Whenever it also displays "STANDBY", it is waiting to give the user time to perform some action before pressing **Continue** to proceed with the current test.

To interrupt a test sequence in Auto Mode, stop test if one is in progress (**Softkey 2**), and press **Escape**.

Programmable User Tests

ME Preset Tests

Remote Control of ZODIAC 901

Continue

Escape

6.1 MADSEN ELECTRONICS PRESET TEST MENU

Pressing **Auto Test** accesses one of two parallel menus, the ME Preset Test Menu or User Test Menu. Press **Auto Test** again to select the other test menu, and to toggle between these two menus.

Auto Test

The ME Preset Test Menu enables the operator to start any of the five automatic factory defined tests listed below by pressing the corresponding **Softkey**.

These tests are defined by Madsen Electronics and programmed at the factory—there is no provision for the user to alter them. Each of them includes provision to change the patient I.D. and the ear at the start of the test. Each Madsen Electronics Preset Test performs a Print All when the last measurement is complete.

"Screen" performs a Tymp. Sweep test and then an Ipsi Reflex Screening test (1000 Hz, 95 dB HL), followed by printout (Print All).

Softkey 1

Softkey 2

"T&R" performs a Tymp. Sweep and then Reflex Threshold, Ipsi, with 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz stimuli in turn, followed by printout (Print All).

Softkey 3

"T&Decay" performs a Tymp. Sweep, Reflex Threshold, Ipsi, at 1000 Hz, followed by Ipsi Reflex Decay at 1000 Hz (Level: +10 dB) and finally printout (Print All).

Softkey 4

"T&Fscr. Ipsi" performs a Tymp. Sweep and Ipsi Reflex Threshold Fast Screening, at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz, followed by printout (Print All).

Softkey 5

"T&Fscr. Contra" performs a Tymp. Sweep and Contra Reflex Threshold Fast Screening, at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz, followed by printout (Print All).

Madsen Electronics reserves the right to alter the contents and definition of these Preset Tests at any time without notice.

6.2 USER-PROGRAMMABLE TESTS

ZODIAC 901 is supplied with four user-programmable tests, User 1, User 2, User 3 and User 4. These tests may be uploaded to a PC or downloaded from a PC by means of ZODICON™.

User-Programmable Tests

By user-programmable or user tests, we mean that the user can select the default parameters of a particular test; the user can also select a combination of tests to form a battery of preset tests. The user-programmable tests may be configured as a power-up option (see §7.1).

Auto Test

Toggle **Auto Test** to enter the User Test Menu. The bottom line of the display will contain the names of any User Tests which have been programmed, otherwise there will only be dashes.

7. POWER-ON OPTIONS

Two of the function keys, Auto Test and Setup, may be used to initiate extra facilities. This is achieved by holding down the chosen function key while powering the instrument on. These facilities are used, if required, not during patient testing, but in the course of preparations for testing, and this method of access protects the user against their accidental alteration or misuse. There are two different facilities that may be accessed in this way—User Test Programming, and ZODIAC 901 System Setup. User Test Programs and changes made to parameters using System Setup will be preserved in the non-volatile memory of the ZODIAC 901 when the power is switched off, and will remain in effect unless altered again subsequently using the Power-On facility.

7.1 USER TEST PROGRAMMING

The purpose of the User Test Programming Mode is to permit the user to program his own tests (Tests 1–4 in the User Test Menu accessed from **Auto Test**).

By user-programmable or user tests, we mean that the user can select the default parameters of a particular test; the user can also select a combination of tests to form a battery of preset tests.

To enter User Test Programming Mode, switch off the instrument and power it on again with **Auto Test** held down. Keep it held down until the message “Programming Mode Enabled” appears on the display; then release it.

The ZODIAC 901 carries out the normal self-test procedure. When this has finished, the Main Menu appears. To continue with user programming, press **Auto Test** again. The User Test Menu screen shown in Fig.7.1 appears (here Test 1 has previously been saved as PEN).

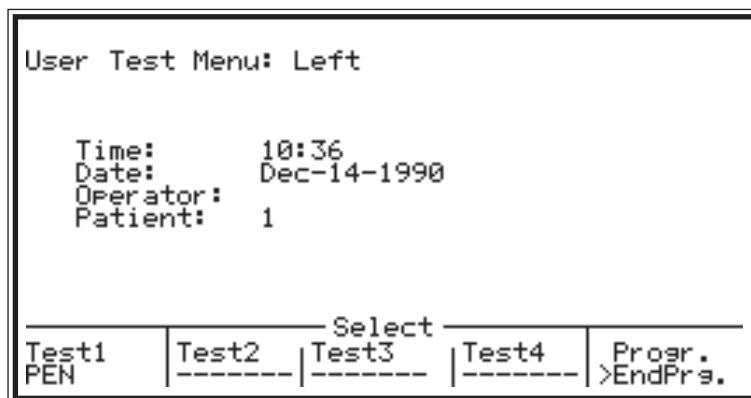


Fig.7.1

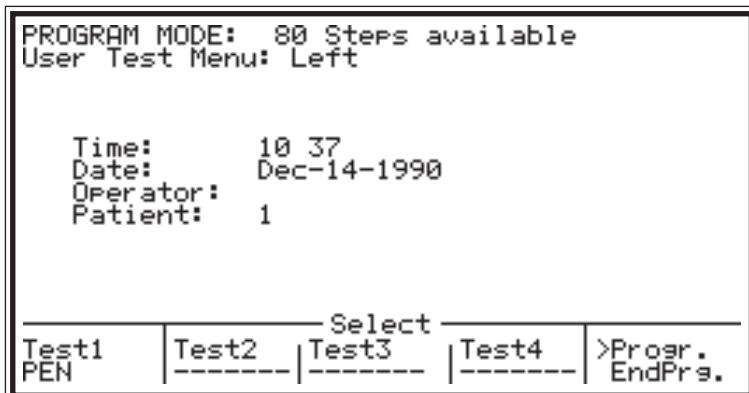
User Test Menu: Programming Mode Enabled

Softkey 5

Press **Softkey 5** to start programming to enter the Program Menu, Fig.7.2. The top line of this menu indicates how many steps are available.

Fig.7.2

Program Mode Select menu before programming

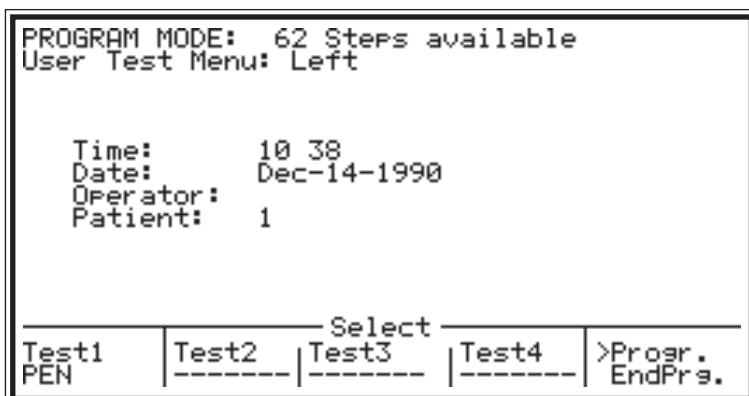


Softkeys 1 to 4

Press **Softkey 1, 2, 3 or 4** to select the test you wish to program. It is then possible to define a test by simply operating the instrument in the normal way—ZODIAC 901 will memorize all your key entries and settings. The number of program steps for which the current test has memory available will be displayed at the top of the screen, and will be reduced by 1 each time a further program step is added—see Fig.7.3).

Fig.7.3

Program Mode Select menu during programming



Continue

Use **Continue** to insert pauses in your test sequence for inspecting curves, altering Setup parameters or operating the instrument manually. The beeper sounds each time **Continue** is pressed. It will also sound each time a pause is encountered when the program is run.

Auto Test

After entering the last step in the User Test Programming sequence, press **Auto Test** to return to the Program Menu.

Softkey 5

Press **Softkey 5** to end programming. This displays the Program Mode Operation screen shown in Fig.7.5, which allows you to enter a name for the test you have just programmed.

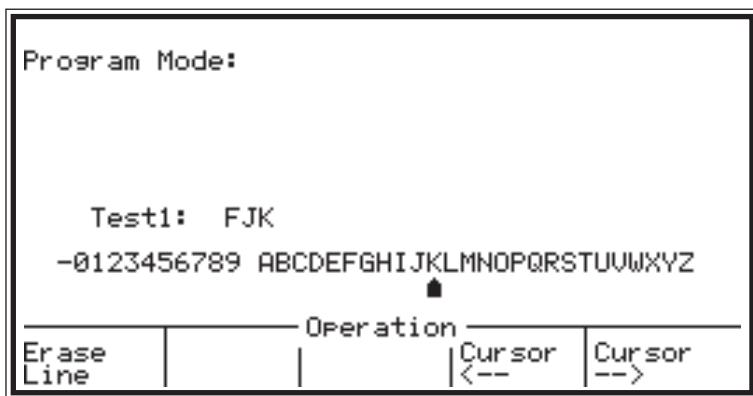


Fig.7.5

Program Mode: Entering name of test

Erase the previous name by means of **Softkey 1**, and enter the new program name in the same way as for operator and patient I.D. (described in §3.4.2).

Softkey 1

Press **Auto Test** again to save the new test program. You are asked to confirm that you really wish to save it (thus overwriting the old one)—Fig.7.4.

Auto Test

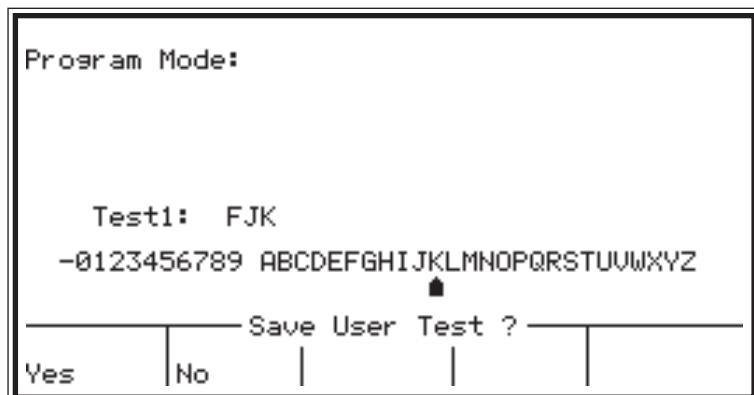


Fig.7.4

Program Mode Save Confirmation menu

Press **Softkey 1** to save and you are returned to the first screen in the programming sequence (see Fig.7.1).

Softkey 1

Press any key to exit this screen and enter the desired test mode.

To Exit

Whenever the test which has been programmed is subsequently accessed, exactly the same sequence will be repeated, and your Setup settings restored ("Automatic Mode" and status will be displayed at the top of the screen).

If you have programmed a break or pause into your test sequence, you will hear a beep when the break is reached and "STANDBY" will appear in the top line.

To continue, press **Continue**.

Continue

To interrupt or exit a test sequence, first press **Softkey 2** (Stop) if a test is running, and then **Escape**.

Escape

An example of a simple program sequence is given below (in Advanced Mode). This sequence performs an automatic tympanogram sweep on each ear in turn, with A.F.A.P. pump speed and auto scaling, prints the two tympanograms out, and advances the patient counter. One pause is included, to allow the operator to insert the probe into the patient's other ear. Execute the following keystrokes from the Program Mode Select menu, see Fig.7.2:

Softkey 1 (Test1)
Tymp.
Softkey 2 (Sweep)
Setup
Softkey 1 (Pump Speed: A.F.A.P)
Softkey 3 (Scaling: 4.5 ml)
Softkey 3 (Scaling: Auto)
Setup
Softkey 2 (Start)
Standby
Alt. Select
Softkey 4 (L/R)
Softkey 2 (Start)
Printer
Softkey 3 (Print All)
Alt. Select
Softkey 4 (L/R)
Main Menu
Softkey 1 (New Pt.)
Softkey 1 (Yes)
Auto Test
Softkey 5 (End Program)
Enter Test Name (use rotary switch)
Auto Test
Softkey 1 (save user test)
Power instrument off (to disable programming mode)

Auto Test

Now power instrument on again, press **Auto Test** and **Softkey 1** to start your own User Test.

Use Default Config.

NOTE: Since existing test parameters are included in your User Test, we suggest that you return the instrument to its default configuration immediately after starting to program User Tests—Main Menu, Softkey 4 (Default Config.), Softkey 1.

7.2 SYSTEM SETUP

Changes made to parameters using System Setup will be preserved in the non-volatile memory of the ZODIAC 901 when the power is switched off, and will remain in effect unless altered again subsequently using the System Setup facility. To enter this mode, switch off the instrument, and power it on again with **Setup** held down. Keep it held down until the screen shown in Fig.7.6, System Setup, appears.

Setup

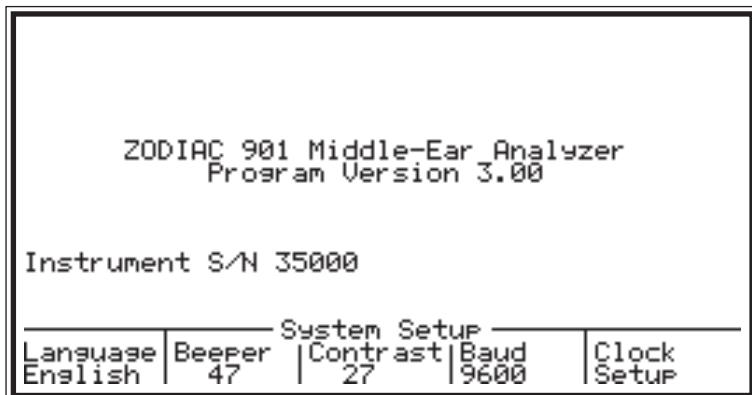


Fig.7.6

ZODIAC 901 System Setup menu

Pressing **Softkey 1** scrolls through the languages available for the text on the Liquid Crystal Display and printouts. Alternatively, hold **Softkey 1** down and turn the **Rotary Knob** clockwise or anticlockwise. Earlier versions of the ZODIAC 901 allow a choice of English, Italian, Spanish and German. Version 2.03 and higher also include French.

Softkey 1

Hold down **Softkey 2** and turn the **Rotary Knob** to adjust the sound level of the beeper.

Softkey 2

Hold down **Softkey 3** and turn the **Rotary Knob** to adjust the contrast.

Softkey 3

Press **Softkey 4** to scroll through the different baud rates (300, 600, 1200, 2400, 4800, 9600)—the baud rate determines the speed of data transfer when communicating with an external computer. Alternatively, hold down **Softkey 4** and turn the **Rotary Knob** clockwise or anticlockwise.

Softkey 4

IMPORTANT! The baud rate must be set to the correct value (9600 baud) when communicating with MIDIMATE 622 or MateBaseI.

Selecting Baud Rate
for External
Communications

Softkey 5

Press **Softkey 5** to access the screen shown in Fig.7.7.

Fig.7.7

Real-Time Clock Setup menu



Softkey 1

- Press **Softkey 1** to select 12 or 24 hour time format.

Softkey 3

- Pressing **Softkey 3**, Select, toggles between Time and Date (as can be seen from the cursor to the left of the words Time and Date in the display).

Softkeys 4/5

- The smaller cursor indicates the unit of time to be altered. Use arrow controls (**Softkeys 4/5**) to select desired unit.
- Turn the **Rotary Knob** to change unit (the **Tone Switch** may also be used here to select unit).

The date goes up to Dec-31-2190! Note that the Date Format (date-Month-Year is the factory default) can be changed by means of ZODICON™.

Setup

Press **Setup** to return to the previous display, and **Setup** again to exit. The ZODIAC 901 then goes through the normal self-test procedure.

8. PRINCIPLES OF MIDDLE-EAR ANALYSIS

The ZODIAC 901 Middle-Ear Analyzer is designed for screening and clinical diagnosis of audiological patients using objective measurement methods.

The ZODIAC 901 measures the mechanical impedance of the ear, a process known as tympanometry. In contrast to audiometry, mechanical impedance measurements are not influenced by the patient's conscious response to the measurement stimulus.

The real-time measurement capability of the ZODIAC 901 enables it to perform dynamic tests of the patient's reflex, threshold and Eustachian Tube Function.

The following explanation of tympanometry is included in order to provide the user of the ZODIAC 901 with sufficient understanding of the physics and physiology of middle-ear measurement to enable him or her to make the most effective use of this advanced and versatile instrument.

8.1 MECHANICAL IMPEDANCE

Sound is a particular case of mechanical vibration at frequencies within the audible range, namely more than about 20 Hz and less than about 20 000 Hz. Mechanical vibration comprises a backwards-and-forwards motion about a mean position. This motion takes place in the substance transmitting the vibration—no vibration can be transmitted in a vacuum.

Sound and vibration

The backwards-and-forwards motion is characterized by changes in vibration pressure p which are proportional to the vibration velocity c of the motion (except at very large amplitudes where the substance may become nonlinear).

$$p = c \ Z$$

The constant of proportionality, Z , is known as the mechanical impedance. It is a characteristic of the substance or structure which is subject to the vibration. Stiff, dense substances such as bone have relatively high mechanical impedances, since a large pressure is required to produce a small deflection (or motion). Air has a relatively low mechanical impedance, since it is neither stiff nor dense, and a small pressure results in a relatively large deflection.

Mechanical impedance

In the special case of audible vibrations, the term "acoustic impedance" is used instead of "mechanical impedance".

Acoustic impedance

The reciprocal of Z is the mechanical, or acoustical, admittance. The term “acoustic immitance” is used collectively to refer to either of these parameters.

Measurement of changes in the acoustic impedance of the ear forms the basis for tympanometry.

8.2 MISMATCHING OF MECHANICAL IMPEDANCES

During the transmission of a mechanical vibration through a homogeneous medium or along a homogeneous transmission line, the ratio of vibration pressure to vibration velocity is equal to the characteristic mechanical impedance of the transmission medium.

Mismatching of impedances

If the vibration encounters an inhomogeneity in its passage, i.e., a region where the mechanical impedance changes from one value to another, then, in general, a part of the energy in the vibration will be reflected back towards the source, and only a proportion of the energy will continue in the direction of the original wave, past the inhomogeneity. The impedances are said to be mismatched.

In a system whose purpose is to transmit vibrational energy, such as the ear, this is a functional disadvantage, since some of the energy fails to arrive at its intended destination. An inhomogeneity in this kind of system is most likely to arise at a boundary between adjoining components of the system.

8.3 MATCHING OF MECHANICAL IMPEDANCES

Matching of impedances

The ear collects as much as possible of the acoustic energy arriving at the ear-lobe by means of two natural mechanisms which minimize reflections.

- The structure of the outer ear is such as to effect a continuous transition from the relatively low mechanical impedance of the open air to the intermediate impedance of the eardrum.
- The middle ear incorporates a mechanical broad-band impedance transformer. A broad-band transformer is a device whose structure is such that it presents differing impedances at its input and output.

8.4 RESISTIVE LOSS OF VIBRATION ENERGY

Resistive loss of vibration energy

Resistive loss occurs when a mechanical vibration or sound wave passes through a material which is subject to hysteresis, and part of the energy is absorbed into the material, and thereby converted into heat.

Hysteresis is a common feature of practical compliant materials. It is characterized by a difference in the deflection resulting from the application of a given pressure, depending upon whether the pressure is increasing or decreasing.

Hysteresis

Although resistive loss results in a reduction of the amplitude of a wanted vibration, it can also be beneficial in systems such as the human ear. It can dampen the effects of resonances and standing waves. It can also play its part in achieving matching of mechanical impedance.

Hysteresis in the eardrum may be observable in tympanometry if two different tympanograms are produced from the same ear measured under conditions which are identical except for the sweep direction. However, this effect could also be caused by too great a pump speed.

8.5 THE STRUCTURE OF THE EAR

The ear comprises the parts of the body which convert sound waves into impulses in the human body's central nervous system.

Structure of the Ear

The ear is a highly developed organ, capable not only of detecting, but also of analyzing, weak sounds containing very small amounts of energy. These capabilities are possible because the construction of the ear is such as to minimize the loss of energy incurred by a sound wave in its passage through the ear.

Losses can occur as a result of reflection and absorption of the energy in the sound wave, as discussed above.

Both of these kinds of losses can be pathologically increased by defects of the inner ear. Much of the construction of the healthy ear owes its form to the need to provide an impedance transformation from the low impedance of free space to the relatively high impedance of the inner ear.

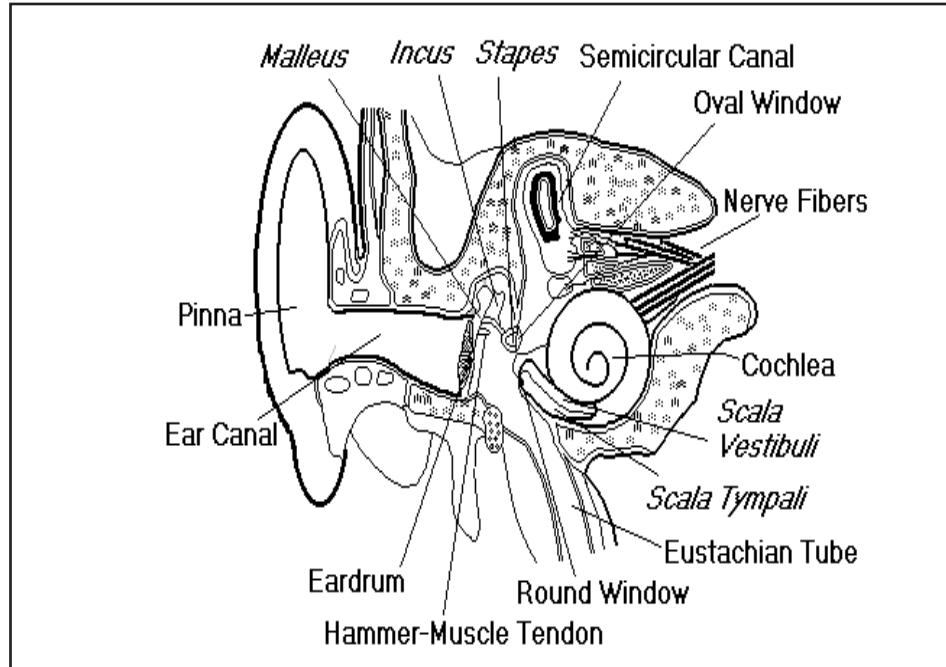
Each ear consists of three main constituents—an outer ear, a middle ear, and an inner ear (Fig.8.1).

The outer ear comprises the visible external ear (*pinna*), plus the auditory canal (ear canal, *meatus*), which is terminated by a delicate membrane, the eardrum (*tympanum*). The outer ear serves to protect the eardrum from damage and provide a continuous impedance transformation from free space to the middle ear. The air in the outer ear is connected to the atmosphere. The bone behind the ear is called the mastoid.

Outer Ear

Fig.8.1

Section through the ear



Middle Ear

The middle ear is an air-filled cavity (the tympanic cavity) connected to the throat, and thence to the atmosphere, by a fine channel, the Eustachian Tube, which serves to prevent the build-up of a pressure differential across the ear-drum. The healthy Eustachian Tube is normally obstructed except during swallowing.

Auditory Ossicular Chain

In the middle-ear cavity is a structure of three tiny bones—hammer (*malleus*), anvil (*incus*) and stirrup (*stapes*)—called the auditory ossicular chain, which links the ear-drum to another membrane, the oval window (*fenestra vestibuli ovalis*). Among the attachments between the auditory ossicular chain and the walls of the middle ear is a tendon connecting the stirrup to a tiny muscle, the *stapedius* muscle. The hammer is also subject to the action of a muscle, the *tensor tympani*. When either or both of these two muscles contract, the ear-drum becomes tensioned, and the impedance of the system will be increased.

Inner Ear

The oval window is the component by which sound waves enter the inner ear, in the form of mechanical vibrations. The inner ear (labyrinth) is filled with fluid, and consists of the cochlea, which converts the vibrations into nerve impulses, and the semi-circular canals, which form part of the body's balancing mechanism.

The auditory ossicular chain serves as a broad-band impedance-matching transformer.

8.6 THE EFFECT OF LOUD SOUNDS

The normal condition of the ear-drum is that of a highly compliant membrane which has only a small influence on the impedance presented to acoustic waves travelling through the outer ear. The main constituent

of this impedance is the impedance presented by the oval window, as transformed by the hammer, anvil and stirrup. It is because of this that impedance measurements taken at the entrance to the outer ear can supply detailed information on conditions in the middle and inner ear.

The arrival of very loud sounds in the middle ear would result in overloading of the mechanisms of the ear. This would cause distortion and reduce the effectiveness of the sense of hearing. If the loudness were excessive, permanent damage could occur.

When the central nervous system perceives a rise in sound level in either ear, it issues an instruction to the *tensor tympani* and *stapedius* muscles in both ears to contract. Contraction of these muscles results in a tensioning of the ear-drum. The tense ear-drum presents a higher impedance to the outer ear, and consequently most of the energy in the loud sound is reflected back the way it came.

Stapedius reflex

This mechanism is part of the body's reflex system. It is known as the auditory, or *stapedius*, reflex. It serves as a form of automatic volume control. Its speed and effectiveness may be determined by applying a loud sound to the ear and measuring the timing of the change in the mechanical impedance of the outer ear.

8.7 MEASURING ACOUSTIC IMPEDANCE

If air is injected into a cavity, the pressure inside the cavity will increase. Provided the temperature does not change, and the cavity walls are rigid, the relationship between the volume V and the pressure P will conform to Boyle's Law:

Acoustic impedance

$$P = k / V$$

where k is constant. Differentiating the right-hand expression gives:

$$dP/dV = k \log V$$

i.e.,

$$dP = dV P V \log V$$

This relationship tells us that the change in pressure resulting from the injection of a small, known volume of air dV will depend not only on dV , but also on the initial pressure P and the volume V of the cavity. Since dV and P are known, measuring dP would enable $V \log V$, and hence V , to be calculated.

The practical and convenient way to make this measurement is to use a calibrated electroacoustic transducer to inject a sound wave into the cavity. The resulting value of dP can be measured using a calibrated microphone connected to the cavity.

*Frequency for
tympanometry*

It is important to perform this measurement at a frequency which is not too high, with the undesirable result that the changing pressure in the cavity would cease to be the same everywhere in the cavity. This is an expression of the requirement that the wavelength of the chosen frequency should be much longer than the largest dimension of the cavity. For mechanical or acoustic impedance measurements on the ear, the frequency to be used has been standardized at 226 Hz.

The expression $P V \log V$ is related to the mechanical impedance of the outer ear cavity, but is not equal to it. This is because it relates the acoustic pressure to the change in volume, not to the acoustic velocity. The velocity is a function not only of the change in volume, but also of the frequency. However, at a fixed frequency there will be a one-to-one correspondence between the mechanical impedance and the volume of the cavity. Tympanometry is concerned with measuring, not the absolute value of the mechanical impedance, but changes in its value.

8.8 TENSIONING OF THE EARDRUM

As explained above, the impedance of the healthy ear under normal conditions will be determined not only by the volume of the outer ear, but also by the impedance of the inner ear as transformed by the auditory ossicular chain and presented at the eardrum.

The deflection of the eardrum in response to acoustic vibrations is very small, and its behaviour is normally linear. That is to say, its mechanical impedance is independent of the sound pressure level. Its deflection is proportional to the sound pressure.

*Nonlinearity of the
eardrum*

However, for changes in pressure which are significantly greater than those produced by the normal range of sounds, the deflection of the eardrum is non-linear. Its impedance is no longer independent of the applied pressure. The greater the pressure (or depression), the stiffer it becomes.

If the ear-drum becomes tensioned for any reason, most of the acoustic energy arriving at it will be reflected, and the mechanical impedance measured will be determined predominantly by the volume of the outer ear alone.

The nonlinearity of the eardrum is what makes tympanometry possible.

*Tensioning the
eardrum*

Tensioning of the ear-drum may be achieved by applying a positive or negative standing air pressure to the outer ear. The inner ear normally remains at (or close to) atmospheric pressure provided the ear is healthy, i.e., the Eustachian Tube is functioning correctly. The term "tympanometry" is commonly understood to mean the measurement of mechanical impedance while varying the static (standing) pressure in the outer ear. The resulting mechanical impedance characteristic (the tympanogram) is a very effective indicator of conditions of disorder in the middle ear.

The static pressure or depression typically required to tension the eardrum sufficiently to reflect half of the sound power impinging on it is 300 Pa, i.e., 0.3% of atmospheric pressure. This may be compared with the RMS (root means square) sound pressure of the threshold of pain, which is around 100 Pa (at the entrance to the ear canal).

Notice that a static pressure of this magnitude will not cause any pain or discomfort in the healthy ear, unlike an acoustic pressure of the same magnitude.

The ear-drum may also be tensioned by the application of a loud sound to either ear, resulting in the contraction of the middle-ear muscles of both ears. The term "audiological reflex", or simply "reflex", is commonly taken to refer to the measurement of mechanical impedance during the application and removal of a loud sound, either to the same ear ("ipsi"), or to the other ear ("contra"). This phenomenon may be observed and measured at a sound pressure level considerably below the threshold of pain.

Audiological reflex

8.9 THE PRINCIPLE OF TYMPANOMETRY

The method used by the ZODIAC 901 for measuring the impedance of the ear canal is sometimes referred to as acoustic-flow tympanometry. The entry to the ear canal is sealed using a suitably dimensioned eartip, and a probe inserted through the eartip. The probe contains three fine air channels. One is connected to a pump which can raise or depress the static pressure in the ear canal. A second carries a source of sound of known amplitude, referred to as the probe tone. The third gives access to a calibrated measuring microphone, which is used to measure the resulting sound level in the ear canal.

*Acoustic-flow
tympanometry*

The amplitude of the sound needed to produce a given measured sound level in the ear canal will be proportional to the volume of the canal. The ZODIAC 901 uses this principle to calculate the volume. If the eardrum has been tensioned, giving it a large impedance mismatch, so that it reflects most of the sound energy arriving at it, the calculated volume will be that of the outer ear alone. However, if the eardrum is functioning normally, so that most of the sound energy arriving at it is transmitted onwards to the inner ear, the calculated volume will be considerably greater. Intermediate states of the eardrum will result in intermediate calculated volumes.

*Reflection of sound at
the eardrum*

*Cartesian
tympanometry*

Tympanometry is the measurement of the change in the ear canal volume resulting from the tensioning of the eardrum by the application of varying pressure in the ear canal. A tympanogram is a Cartesian graphical representation of this measurement.

Reflex tympanometry

Reflex tympanometry is the measurement of the change in the ear canal volume (the "Delta" volume) resulting from the tensioning of the eardrum by muscles acting on the ossicular chain following the application of an external acoustic stimulus. The results are plotted on a Cartesian graph with time along the x -axis.

The difference between the tympanometric graphs generated from measurements on healthy ears, and those obtained in cases of hearing disorders, allow reliable diagnosis to be made of the nature of the disorders. The real-time computing power of the ZODIAC 901 enables these informative graphs to be generated quickly, repeatedly and accurately.

8.10 PRACTICAL CONSIDERATIONS

*Calibration for
tympanometry*

The volume of air measured using acoustic-flow tympanometry can be expected to be influenced by such variable factors as barometric pressure. The ZODIAC 901 provides for the elimination of the influence of these factors by means of an automatic daily calibration procedure, using a Madsen Electronics Precision Cavity with a known volume of 2.0 cc (2.0 ml).

Because the absolute values of acoustic impedance are influenced by barometric pressure and other variable factors, practical tympanometry concentrates on relative volume measurements, which are used as analogs of impedance.

*Ordinary
environment for
tympanometry*

The probe tone used to measure the ear canal volume in the ZODIAC 901 is a 226 Hz tone, which is the frequency prescribed by the Standards CEI/IEC 1027:1991 and ANSI S3.39-1987. The electronic circuitry used to measure the sound level in the ear cavity incorporates a highly selective filter, which attenuates sound energy at other frequencies than 226 Hz. This enables accurate measurements to be taken in ordinary environments without the use of a special quiet room. It enables the ear canal volume to be measured continuously during the application of an acoustic reflex stimulus, which can be at a much higher level than the 85 dB SPL used for the 226 Hz probe tone.

8.11 TYMPANOGRAM CHARACTERISTICS

A tympanogram has a number of characteristics which are often used for comparison and diagnosis by audiologists, and can be computed automatically by the ZODIAC 901.

A volume tympanogram is a graph showing the measured volume as a function of pressure. The measured volume will at no point be less than the volume of the ear canal alone (ear canal volume, ECV). It is therefore more instructive to generate a “compliance tympanogram”, in which the origin has been moved up the *y*-axis to lie level with the flat part of the curve. The (measured) volume is related to the compliance and the ECV as follows:

$$\text{volume} = \text{ECV} + \text{compliance}$$

The name “compliance” requires some elucidation. The audiologist is interested in using the tympanogram to determine the compliance of the eardrum. Compliance is conventionally expressed as a displacement divided by a pressure. However, any transmission of sound by the eardrum is equivalent to an enlargement of the volume of the ear canal. What is actually measured is this equivalent change in volume, which is a useful representation of compliance for diagnostic purposes.

The eardrum will be most compliant when the static pressures on opposite surfaces of the eardrum are equal or only slightly different. The peak (maximum) of the tympanogram occurs at this pressure, which may differ from atmospheric pressure, depending on conditions in the middle ear. The difference between the pressure at which the peak occurs and atmospheric pressure is therefore referred to as the Middle Ear Pressure (MEP). This pressure is computed and recorded by the ZODIAC 901 when it performs a tympanogram sweep, and can be used automatically for subsequent reflex tests on the same patient.

The maximum increase in measured volume, i.e., the height of the peak on a tympanogram, is the compliance at Middle Ear Pressure. This is known as the Static Compliance (SC). The SC is computed and recorded by the ZODIAC 901 when it performs a tympanogram sweep.

For comparing tympanometric data between patients or between healthy ears and ears subject to disorder, it is helpful to have data which express the shape of the tympanogram rather than its absolute dimensions. After performing a tympanogram sweep, the ZODIAC 901 computes and records two such parameters.

The Gradient (Grad) is the value of compliance at which the width of the “hump” of the tympanogram is 100 daPa, divided by the Static Compliance.

*Volume
tympanogram*

*Compliance
tympanogram*

Middle Ear Pressure

Static Compliance

Gradient

Tympanogram Width

The Tympanogram Width (TW) is the pressure difference between the two points on the curve at which the compliance is half the Static Compliance.

9. DIAGNOSIS OF AUDITORY DISORDERS

9.1 DISORDERS AND THEIR SYMPTOMS

9.1.1 MIDDLE-EAR FLUID AND EFFUSION

Serous otitis is a disease which can lead to a build-up of fluid and a reduced pressure in the middle ear. The resulting middle ear dysfunction with fluid effusion in the middle ear space produces a very shallow tympanogram with a reduced static compliance and a reduced gradient. Only in a small proportion of cases is a peaked tympanogram produced. The pressure reduction results in a tympanogram shifted to the left. Ipsilateral acoustic reflex is often absent.

9.1.2 DISRUPTION OF THE OSSICULAR CHAIN

If there is a discontinuity in the ossicular chain, the impedance of the cochlea and oval window will have little or no influence on the impedance of the eardrum. Disruption of the ossicular chain results in a very tall tympanogram with increased static compliance and increased gradient, or, in some cases, multiple "humps".

If an ipsilateral reflex is detected, then the disruption is likely to be downstream of the hammer. Otherwise, the reflex may be absent.

9.1.3 OTOSCLEROSIS

Otosclerosis and relative fixation of the footplate of the *stapes* tend to result in reduced static compliance (0.2 to 0.4), reduced gradient, and increased tympanogram width. Reflex may be reduced or absent.

9.1.4 PERFORATED EARDRUM

The eardrum may be perforated as a result of trauma or because it has atrophied. The tympanogram will be almost completely flat.

9.1.5 OCCLUDED EUSTACHIAN TUBE

If the Eustachian Tube is occluded (blocked), or fails to open regularly (dysfunction), the pressure in the middle ear will usually become less than atmospheric pressure. The effect will be to shift the tympanogram to the left. The reflex is normally unaffected. If the eardrum is not perforated, this condition may be investigated using the Intact Eardrum test

available in Tymp. Advanced Mode (not Version 2.x of the ZODIAC 901).

9.1.6 FLABBY TYMPANIC MEMBRANE

A flabby (flaccid) tympanic membrane may be due to aging, healed perforations, or surgery. It will result in a static compliance which is greater than normal. Reflexes are usually absent.

9.1.7 IMPACTED CERUMEN (DRIED EAR WAX)

Excessive production of earwax will reduce the Ear Canal Volume, and may completely obstruct the ear canal. In this case the tympanogram will exhibit an absence of a peak.

9.1.8 PATULOUS EUSTACHIAN TUBE

A patulous (spread) Eustachian Tube will not close, with the result that the patient's breathing interferes with hearing. The static compliance will be normal but the tympanogram will be broadened (abnormally large tympanogram width) and may exhibit irregularities because of interference from the patient's breathing. If the eardrum is not perforated, this condition may be investigated using the Intact Eardrum test available in Tymp. Advanced Mode (not Version 2.x of the ZODIAC 901).

9.1.9 COCHLEAR HEARING LOSS

Cochlear and retrocochlear hearing loss will be characterized by increased reflex thresholds and increased air conduction thresholds. The tympanogram should not be affected.

A. APPENDIX: TECHNICAL SPECIFICATIONS

Standards

Audiometric Headset:	ISO 389, ANSI S3.6
Impedance:	IEC 1027, ANSI S3.39
Patient Safety:	EN 60601-1, class I, type B

Compliance Measuring System

Probe Tone:	226 Hz at 85 dB SPL
Total Range:	0.1 ml to 8.0 ml
Reflex Ranges:	0 to 75 μ l 0 to 150 μ l 0 to 225 μ l 0 to 300 μ l 0 to 375 μ l Auto scaling and definition of positive, negative or both types of axis
Display Range	
Tympanogram:	0 to 1.5 ml 0 to 3.0 ml 0 to 4.5 ml

Air Pressure System

Range:	Normal:+200 to -400 daPa Extended:+400 to -600 daPa
Accuracy:	\pm 10% or \pm 10 daPa (whichever is greater)
Air Pump:	Plunger type; stepper motor, digitally controlled. Speeds: as fast as possible (AFAP) 400 daPa/sec 200 daPa/sec 100 daPa/sec 50 daPa/sec Manual speed control
Air Release:	Mechanical safety release valve set to +600 and -800 daPa Manual & automatic air release

Acoustic Reflex

Contralateral Stimulation:	Pure tones: 0.5, 1, 2, 4 kHz Frequency Accuracy \pm 0.5% White Noise Step size: 1, 2, 5, 10 dB Normal range: 50-100 dB HL Extended range: 50-120 dB HL
----------------------------	---

Ipsilateral Stimulation:	Pure tones: 0.5, 1, 2, 4 kHz Frequency Accuracy ± 0.5% Step size: 1, 2, 5, 10 dB Range at 0.5, 1, 2 kHz: 50-115 dB HL Range at 4 kHz: 50-90 dB HL
Audiometric Mode	
Frequency Accuracy:	± 0.5%
Pure Tones:	0.25, 0.5, 1, 2, 3, 4, 6, 8 kHz
Step Size:	1, 2, 5, 10 dB
Normal Range:	0-100 dB HL
Extended Range:	0-120 dB HL
Display	Graphic supertwist LCD with backlighting, 256 lines x 128 dots White text/graphics on blue background
Built-in Printer	
Paper Type:	Thermal
Paper Width:	112 mm, 4.5"
External Printer	Any conventional Centronics printer (inkjet, laser, etc.) may be connected via parallel port. The HP Deskjet 500 generic series is the standard driver (HP 510, 520, etc.,)
RS232C Data Interface	Measuring results, setup and I.D. data, etc., may be communicated to and from ZODIAC 901 via this port
Power Supply	AC 50/60 Hz 100-120 V ± 10% or 200-240 V ± 10%
Power Consumption	Approx. 50 VA
Dimensions	370 x 385 x 120 mm (W x D x H) 14.8" x 15.4" x 4.8"
Weight	
Net Weight	7.6 kg
Miscellaneous	Built-in beeper and clock/calendar; sockets for 2 cc cavity and ear simulator in cabinet.

Also available without built-in printer.

B. APPENDIX: ZODICON™ PARAMETERS

The ZODICON™ software, running on a PC, allows each of the ZODIAC 901 parameters below to be set to any of the corresponding settings listed. Each of the following lists of settings begins with the factory default setting.

Institution's Name:

Line #1: Up to 20 characters
Line #2: Up to 40 characters

General System Parameters:

Default Ear: Left, Right
Default Transducer: IPSI, CONTRA
Default IPSI Freq.: 1000, 2000, 4000, 500 Hz
Default IPSI Level: 70, 75, 80, 85, 90, 95, 100, 105, 50, 55, 60, 65 dB
Default CONTRA Freq.: 1000, 2000, 4000 Hz, White N., 500 Hz
Default CONTRA Level: 70, 75, 80, 85, 90, 95, 100, 105, 50, 55, 60, 65 dB
Default Air Cond. Freq.: 1000, 2000, 3000, 4000, 6000, 8000, 250, 500 Hz
Default Air Cond. Level: 0, 5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105 dB
Default Meter Mode: Off, On
Default Printer: Internal, External, None
Calibration Period Warning: Off, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 month
Date Format: Date-Month-Year, Date-Year-Month, Month-Date-Year, Month-Year-Date, Year-Month-Date, Year-Date-Month

Daily Calibration:

Power-up in Daily Calibration: No, Yes
Cavity #1: 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 1.0 cc
Cavity #2: None, 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0 cc

Easy Mode HOT Keys:

Tymp Key -> Tymp Sweep
Tymp ETF-I
Tymp ETF-P
Tymp Manual
Reflex Manual
Reflex Screening
Reflex Decay
Reflex User1
Reflex User2
Threshold Key -> Threshold Reflex
Threshold FastSCR
Threshold Air Cond.

Internal Printer Controller Type:

IF4113, Madsen

Print-All Sequence**External Printout Specification:**

Page Size: 11, 12 inch
 Left Margin: 5 ... 40 spaces, Off, 1 ... 4 spaces
 Double Size Printout: No, Yes

Tymp Default Setup:

Compliance Scaling: 3.0, 4.5 mL, Auto, 0.3, 0.6, 0.9, 1.5 mL
 Abs. Volume Scaling: 9.0, 3.0, 4.5 mL, 6.0, 7.5 mL
 Sweep Pump Speed: 400 daPa/Sec, AFAP, 50, 100, 200 daPa/Sec
 Sweep Measure Dir.: Neg, Pos
 Manual Measure Dir.: Pos/Neg, Neg, Pos
 Manual Average: Off, On
 Min. Sweep Pressure: -400, -350, -300, -250, -200, -150, -100, -600, -550, -500, -450 daPa
 Max. Sweep Pressure: 200, 250, 300, 350, 400, 100, 150 daPa
 Leak detect: Yes, No

ETF Default Parameters:

ETF Y-Axis: Pos/Neg, Neg, Pos
 ETF X-Axis: 45, 46, ... 98, 99, 10, 11, ... 43, 44 Sec

Reflex And Threshold Default Setup:

Scaling: 150, 225, 300, 375 µL, Auto, 75 µL
 Y-Axis: Pos/Neg, Auto, Neg, Pos
 Pressure Control: Manual, Auto, MEP +5, +10, +15, +20, +25, -25, -20, -15, -10, -5
 Att. Incr.: 5, 10, 1, 2 dB
 Leak detect: Yes, No
 Manual Reflex: Multi Curves, Single Curve
 Use Threshold Level in Decay: Off, +0, +5, +10, +15, +20 dB
 Reflex Fast/Slow Mode: Fast, Slow
 TH Level Incr.: 10, 20, -20, -10, -5, -2, -1, 1, 2, 5 dB
 TH FastSCR Max. Meas.: 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 1, 2
 Add. Threshold Search: Off, 0, 5, 10 dB
 Use Pump in TH AirCond.: No, Yes

Threshold Detection Criteria:

TH Detect Delta Volume: 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 10, 15 µL
 TH Detection Time: 500, 600, 700, 800, 900, 1000, 100, 200, 300, 400 mSec
 TH Detection Dir: Neg., Pos./Neg.

Reflex Manual Timing:

X-Axis: 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 2, 3 Sec
 PreTime: 0.5, 0.6, ... 3.4, 3.5, 0.1, 0.2, 0.3, 0.4 Sec
 PostTime: 0.5, 0.6, ... 3.8, 3.9, 0.1, 0.2, 0.3, 0.4 Sec

Reflex Screening Timing:

X-Axis: 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 Sec
 PreTime: 0.5, 0.1, 0.2, 0.3, 0.4 Sec
 StimTime: 2.0, 2.1, 2.2, 2.3, 2.4, 0, 0.1, ... 1.9 Sec
 PostTime: 0.5, 0.6, ... 2.8, 2.9, 0.1, 0.2, 0.3, 0.4 Sec

Reflex Decay:

Timing:

X-Axis: 12, 13, 14, 15, 16, 17, 18 Sec
PreTime: 1.0, 1.1, ... 2.0, 0.1, 0.2, ... 0.9 Sec
StimTime: 10.0, 10.1, ... 11.7, 11.8, 0.0, 0.1, ... 9.8, 9.9 Sec
PostTime: 1.0, 1.1, ... 12.7, 12.8, 0.1, 0.2, ... 0.8, 0.9 Sec

Speed:

Slow, Fast

Reflex User1 Timing:

X-Axis: 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 Sec
PreTime: 0.5, 0.1, 0.2, 0.3, 0.4 Sec
StimTime: 2.0, 2.1, 2.2, 2.3, 2.4, 0, 0.1, ... 1.8, 1.9 Sec
PostTime: 0.5, 0.6, ... 2.8, 2.9, 0.1, 0.2, 0.3, 0.4 Sec

Reflex User2 Timing:

X-Axis: 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 Sec
PreTime: 0.5, 0.1, 0.2, 0.3, 0.4 Sec
StimTime: 5.0, 0.0, 0.1, ... 4.8, 4.9 Sec
PostTime: 0.5, 0.6, ... 3.3, 3.4, 0.1, 0.2, 0.3, 0.4 Sec

Threshold Reflex Timing:

X-Axis: 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 Sec
PreTime: 0.5, 0.1, 0.2, 0.3, 0.4 Sec
StimTime: 1.5, 0.0, 0.1, ... 1.3, 1.4 Sec
PostTime: 1.0, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9 Sec

Threshold FastSCR Timing:

X-Axis: 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 Sec
PreTime: 0.3, 0.1, 0.2 Sec
StimTime: 1.2, 1.3, 1.4, 0, 0.1, ... 1.0, 1.1 Sec
PostTime: 0.5, 0.6, ... 1.8, 1.9, 0.1, 0.2, 0.3, 0.4 Sec

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